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# Contents

Federal Register

Vol. 82, No. 10

Tuesday, January 17, 2017

## Agriculture Department

See Animal and Plant Health Inspection Service

See Rural Utilities Service

## Animal and Plant Health Inspection Service

### PROPOSED RULES

Imports:

Hass Avocados From Colombia, 4798

## Antitrust Division

### NOTICES

Changes under the National Cooperative Research and Production Act:

UHD Alliance, Inc., 4923

## Centers for Disease Control and Prevention

### NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 4884–4886

## Centers for Medicare & Medicaid Services

### RULES

Medicare Program:

Changes to Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures, 4974–5140

### NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 4887–4888

## Civil Rights Commission

### NOTICES

Meetings:

Delaware Advisory Committee; Correction, 4841

## Coast Guard

### RULES

Security Zones:

Annual Events in Captain of the Port Detroit Zone—North American International Auto Show, Detroit River, Detroit, MI, 4794–4795

## Commerce Department

See Foreign-Trade Zones Board

See Industry and Security Bureau

See International Trade Administration

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

See National Telecommunications and Information Administration

## Community Living Administration

### NOTICES

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

Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities, 4889–4890

Protection and Advocacy for Traumatic Brain Injury Program Performance Report, 4888–4889

## Defense Department

See Navy Department

### NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 4863

Charter Amendments, Establishments or Renewals:

Charter Amendment of Department of Defense Federal Advisory Committees, 4862–4863

Department of Defense Federal Advisory Committees; Termination, 4863

## Energy Department

### NOTICES

Meetings:

Nuclear Energy Advisory Committee, 4864

## Environmental Protection Agency

### RULES

Guideline on Air Quality Models:

Enhancements to AERMOD Dispersion Modeling System and Incorporation of Approaches to Address Ozone and Fine Particulate Matter, 5182–5235

National Emissions Standards:

Radon Emissions from Operating Mill Tailings, 5142–5180

### PROPOSED RULES

Procedures for Prioritization of Chemicals for Risk

Evaluation under Toxic Substances Control Act, 4825–4837

Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water, 4805–4825

### NOTICES

California State Motor Vehicle Pollution Control Standards:

Amendments to On-Highway Heavy-Duty Vehicle In-Use Compliance Program, 2007 and Subsequent Model Year On-Highway Heavy-Duty Engines and Vehicles, Truck Requirements, 4867–4873

Emission Guidelines for Greenhouse Gas Emissions and

Compliance Times for Electric Utility Generating Units: Denial of Reconsideration and Administrative Stay, 4864–4866

Proposed Consent Decrees under Clean Air Act Citizen Suit, 4866–4867

## Executive Office for Immigration Review

### RULES

Eliminating Exception to Expedited Removal Authority for Cuban Nationals Arriving by Air, 4771–4773

## Federal Aviation Administration

### RULES

Airworthiness Directives:

Airbus Airplanes, 4773–4775

The Boeing Company Airplanes, 4775–4781

### PROPOSED RULES

Class E Airspace; Amendments:

Atlantic City, NJ, 4798–4800

### NOTICES

Waivers for Aeronautical Land-Use Assurance:

Chicago Midway International Airport, Chicago, IL, 4957–4958

**Federal Communications Commission****PROPOSED RULES**

Petitions for Reconsideration of Action in Rulemaking  
Proceeding, 4837

**NOTICES**

Agency Information Collection Activities; Proposals,  
Submissions, and Approvals, 4873–4880

**Federal Deposit Insurance Corporation****NOTICES**

Terminations of Receivership:  
10359—Community Central Bank Mount Clemens, MI,  
4880

**Federal Election Commission****NOTICES**

Meetings; Sunshine Act, 4880

**Federal Highway Administration****NOTICES**

Environmental Impact Statements; Availability, etc.:  
Tampa Interstate System; Hillsborough County, FL, 4958–  
4959

**Federal Motor Carrier Safety Administration****RULES**

Unified Registration System; Suspension of Effectiveness,  
5292–5318

**Federal Reserve System****NOTICES**

Agency Information Collection Activities; Proposals,  
Submissions, and Approvals, 4880–4884  
Formations of, Acquisitions by, and Mergers of Bank  
Holding Companies, 4883

**Federal Transit Administration****NOTICES**

Agency Information Collection Activities; Proposals,  
Submissions, and Approvals, 4963–4964  
Buy America Handbook:  
Conducting Pre-Award and Post-Delivery Audits for  
Rolling Stock Procurements, 4959–4963  
General Directives:  
17–1: Stop Signal Overruns on Rail Fixed Guideway  
Public Transportation Systems, 4964–4965

**Fish and Wildlife Service****NOTICES**

Permit Applications:  
Endangered Species, 4914–4915

**Food and Drug Administration****PROPOSED RULES****Guidance:**

Control of *Listeria monocytogenes* in Ready-To-Eat  
Foods, 4803–4805

**NOTICES****Guidance:**

Comparative Analyses and Related Comparative Use  
Human Factors Studies for Drug-Device Combination  
Product Submitted in Abbreviated New Drug  
Application, 4890–4892

Compliance Policy for Required Warning Statements on  
Small-Packaged Cigars, 4892–4893

Interpretation of and Compliance Policy for Certain Label  
Requirement; Applicability of Certain Federal Food,  
Drug, and Cosmetic Act Requirements to Vape  
Shops, 4893–4894

Referencing Approved Drug Products in Abbreviated New  
Drug Application Submissions, 4894–4896

**Meetings:**

Strategic Partnerships to Enhance Safety of Imported  
Foods: Capacity Building, Risk-Based  
Decisionmaking, Recognition of Commodity Food  
Control Programs, and Systems Recognition, 4896–  
4899

**Foreign Assets Control Office****RULES**

Sudanese Sanctions Regulations, 4793–4794

**NOTICES**

Blocking or Unblocking of Persons and Properties, 4967

**Foreign-Trade Zones Board****NOTICES****Proposed Production Activities:**

IRIS USA, Inc., Foreign-Trade Zone 277, Western  
Maricopa County, AZ, 4842

**Reorganizations under Alternative Site Framework:**

Foreign-Trade Zone 124, Gramercy, LA, 4841–4842

**Health and Human Services Department**

*See* Centers for Disease Control and Prevention

*See* Centers for Medicare & Medicaid Services

*See* Community Living Administration

*See* Food and Drug Administration

*See* Health Resources and Services Administration

**Health Resources and Services Administration****NOTICES**

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

National Hospital Organ Donation Campaign's Activity  
Scorecard, 4899–4900

**Homeland Security Department**

*See* Coast Guard

*See* U.S. Citizenship and Immigration Services

*See* U.S. Customs and Border Protection

**RULES**

Eliminating Exception to Expedited Removal Authority for  
Cuban Nationals Arriving by Air, 4769–4771

International Entrepreneur Rule, 5238–5289

**NOTICES**

Eliminating Exception to Expedited Removal Authority for  
Cuban Nationals Encountered in United States or

Arriving by Sea, 4902–4905

**Meetings:**

National Infrastructure Advisory Council, 4902

**Housing and Urban Development Department****NOTICES**

Community Development Block Grant Disaster Recovery  
Grant Program:

Waiver of Requirements for State of New York for  
Recovery of Lower Manhattan, 4911–4913

Order of Succession for Office of Strategic Planning and  
Management, 4913

**Indian Affairs Bureau****NOTICES**

Indian Entities Recognized and Eligible to Receive Services  
from United States Bureau of Indian Affairs, 4915–4920

**Land Acquisitions:**

Craig Tribal Association, Craig, AK, 4915

**Industry and Security Bureau****RULES**

Revisions to Sudan Licensing Policy, 4781–4783

**NOTICES**

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

Voluntary Self-Disclosure of Antiboycott Violations, 4842

Orders:

Berty Tyloo, 4842–4844

**Interior Department**

See Fish and Wildlife Service

See Indian Affairs Bureau

See Land Management Bureau

See National Park Service

**International Trade Administration****NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Ammonium Sulfate from People's Republic of China, 4850–4852

Certain Corrosion-Resistant Steel Flat Products from Republic of Korea, 4846–4848

Chlorinated Isocyanurates from People's Republic of China, 4852–4853

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from People's Republic of China, 4844–4846

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from People's Republic of China; Final Results of Changed Circumstances Review and Reinstatement of Shanghai General Bearing Co., Ltd., 4853–4855

Determinations of Sales at Less Than Fair Value:

Certain New Pneumatic Off-the-Road Tires from India, 4848–4850

**International Trade Commission****NOTICES**

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

Certain Industrial Control System Software, Systems Using Same and Components Thereof, 4922–4923

**Justice Department**

See Antitrust Division

See Executive Office for Immigration Review

**RULES**

Formula Grant Program:

Juvenile Justice and Delinquency Prevention Act, 4783–4793

**NOTICES**

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

Office for Victims of Crime Training and Technical Assistance Center–Trafficking Information Management System, 4923–4924

**Labor Department****NOTICES**

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

Notice of Law Enforcement Officer's Injury or Occupational Disease; Notice of Law Enforcement Officer's Death, 4924–4925

**Land Management Bureau****NOTICES**

Public Land Orders:

Partial Revocation of Withdrawal, Lonesome Lake Reservoir, MT, 4920–4921

**National Credit Union Administration****NOTICES**

Meetings; Sunshine Act, 4925

**National Institute of Standards and Technology****NOTICES**

Meetings:

Visiting Committee on Advanced Technology; Correction, 4855

**National Oceanic and Atmospheric Administration****NOTICES**

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

Atlantic Sea Scallops Amendment 10, 4859–4860

Endangered Species

Endangered Species; File No. 19508, 4855–4856

Exempted Fishing Permits; Applications, 4856–4858

Meetings:

Mid-Atlantic Fishery Management Council, 4861

North Pacific Fishery Management Council, 4856

Pacific Fishery Management Council, 4859

Permits:

Marine Mammals; File No. 20043, 4858–4859

Marine Mammals; File Nos. 19703 and 20993, 4860–4861

**National Park Service****NOTICES**

Environmental Impact Statements; Availability, etc.:

Off-road Vehicle Management Plan, Glen Canyon

National Recreation Area, Arizona and Utah, 4921–4922

**National Telecommunications and Information Administration****NOTICES**

Meetings:

Multistakeholder Process on Internet of Things Security Upgradability and Patching, 4861–4862

**Navy Department****NOTICES**

Government-Owned Inventions; Availability for Licensing, 4864

Meetings:

Ocean Research Advisory Panel, 4863–4864

**Nuclear Regulatory Commission****NOTICES**

Applications and Amendments Involving Proposed No

Significant Hazards Considerations, etc., 4926–4938

Category 3 Source Security and Accountability; Correction, 4938

Guidance:

Possession Licenses for Production of Radioactive Material Using Accelerator, 4925–4926

**Pipeline and Hazardous Materials Safety Administration****NOTICES**

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

Hazardous Materials, 4965

**Presidential Documents****EXECUTIVE ORDERS**

Decorations, Medals, Awards:

Purple Heart Eligibility Criteria; Amendment to Executive Order 11016 To Update (EO 13758), 5319–5322

Government Agencies and Employees:

Federal Labor-Management Relations Program; Exclusions (EO 13760), 5325–5329

World Organisation for Animal Health; Designating as a Public International Organization Entitled To Certain Privileges, Exemptions, and Immunities (EO 13759), 5323–5324

**Rural Utilities Service****NOTICES**

Requests for Applications:

Deadlines and Requirements for Section 313A Guarantees for Bonds and Notes Issued for Electrification or Telephone Purposes Loan Program for Fiscal Year 2017, 4838–4841

**Science and Technology Policy Office****NOTICES**

Meetings:

National Nanotechnology Initiative, 4938

**Securities and Exchange Commission****NOTICES**

Applications:

Brown Advisory, LLC, 4938–4941

Self-Regulatory Organizations; Proposed Rule Changes:

Bats BZX Exchange, Inc., 4954–4956

Bats EDGX Exchange, Inc., 4941–4947

BOX Options Exchange, LLC, 4956

NASDAQ Stock Market, LLC, 4947–4950

NYSE Arca, Inc., 4950–4953

**State Department****NOTICES**

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

Application to Determination Returning Resident Status, 4957

Culturally Significant Objects Imported for Exhibition:

Alexei Jawlensky Exhibition, 4956

Enlightened Princesses: Caroline, Augusta, Charlotte, and the Shaping of the Modern World, 4956–4957

**Surface Transportation Board****RULES**

Civil Monetary Penalties—2017 Adjustment, 4796–4797

**NOTICES**

Release of Waybill Data, 4957

**Transportation Department***See* Federal Aviation Administration*See* Federal Highway Administration*See* Federal Motor Carrier Safety Administration*See* Federal Transit Administration*See* Pipeline and Hazardous Materials Safety Administration**NOTICES**

Solicitation of Proposals for Designation of Beyond Traffic Innovation Centers, 4965–4967

**Treasury Department***See* Foreign Assets Control Office**PROPOSED RULES**

Donations of Technology and Support Services to Enforce Intellectual Property Rights, 4800–4803

**U.S. Citizenship and Immigration Services****NOTICES**

Extension of the Designation of Somalia for Temporary Protected Status, 4905–4911

**U.S. Customs and Border Protection****PROPOSED RULES**

Donations of Technology and Support Services to Enforce Intellectual Property Rights, 4800–4803

**NOTICES**

Automated Commercial Environments:

Sole CBP-Authorized Electronic Data Interchange System for Processing Electronic Drawback and Duty Deferral Entry and Entry Summary Filings, 4900–4901

National Customs Automation Program Tests:

Reconciliation, Post-Summary Corrections, and Periodic Monthly Statements, 4901

**Veterans Affairs Department****RULES**

Repayment by VA of Educational Loans for Certain Psychiatrists; Correction, 4795–4796

**NOTICES**

Loan Guarantees:

Specially Adapted Housing Assistive Technology Grant Program, 4967–4971

**Separate Parts In This Issue****Part II**

Health and Human Services Department, Centers for Medicare &amp; Medicaid Services, 4974–5140

**Part III**

Environmental Protection Agency, 5142–5180

**Part IV**

Environmental Protection Agency, 5182–5235

**Part V**

Homeland Security Department, 5238–5289

**Part VI**

Transportation Department, Federal Motor Carrier Safety Administration, 5292–5318

**Part VII**

Presidential Documents, 5319–5329

**Reader Aids**

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

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

**CFR PARTS AFFECTED IN THIS ISSUE**

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

**3 CFR****Executive Orders:**

11016 (Amended by 13758).....	5321
12171 (Amended by 13760).....	5325
13758.....	5321
13759.....	5323
13760.....	5325

**7 CFR****Proposed Rules:**

319.....	4798
----------	------

**8 CFR**

103.....	5238
212.....	5238
235.....	4769
274a.....	5238
1235.....	4771

**14 CFR**

39 (3 documents) ...	4773, 4775, 4778
----------------------	---------------------

**Proposed Rules:**

71.....	4798
---------	------

**15 CFR**

742.....	4781
----------	------

**19 CFR****Proposed Rules:**

133.....	4800
----------	------

**21 CFR****Proposed Rules:**

117.....	4803
----------	------

**28 CFR**

31.....	4783
---------	------

**31 CFR**

538.....	4793
----------	------

**33 CFR**

165.....	4794
----------	------

**38 CFR**

17.....	4795
---------	------

**40 CFR**

51.....	5181
61.....	5142

**Proposed Rules:**

141.....	4805
143.....	4805
702.....	4825

**42 CFR**

401.....	4974
405.....	4974
422.....	4974
423.....	4974
478.....	4974

**47 CFR****Proposed Rules:**

64.....	4837
---------	------

**49 CFR**

360.....	5292
365.....	5292
366.....	5292
368.....	5292
385.....	5292
387.....	5292
390.....	5292
1022.....	4796

# Rules and Regulations

Federal Register

Vol. 82, No. 10

Tuesday, January 17, 2017

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

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

#### 8 CFR Part 235

[DHS Docket No. DHS–2017–0003]

RIN 1601–AA81

#### Eliminating Exception to Expedited Removal Authority for Cuban Nationals Arriving by Air

**AGENCY:** Office of the Secretary, Department of Homeland Security.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This final rule revises Department of Homeland Security (DHS) regulations to eliminate the categorical exception from expedited removal proceedings for Cuban nationals who arrive in the United States at a port of entry by aircraft. As a result of these changes, Cuban nationals who arrive in the United States at a port of entry by aircraft will be subject to expedited removal proceedings commensurate with nationals of other countries.

**DATES:** This final rule is effective January 13, 2017. Interested persons are invited to submit written comments on this final rule on or before March 20, 2017.

**ADDRESSES:** You may submit comments, identified by Regulatory Information Number (RIN) 1601–AA81 and DHS Docket Number DHS–2017–0003, by any one of the following methods:

- *Federal e-Rulemaking Portal* [www.regulations.gov](http://www.regulations.gov). Follow the Web site instructions for submitting comments.

- *Mail or Hand Delivery/Courier:* Please submit all written comments (including and CD-ROM submissions) to Amanda Baran, Principal Director for Immigration Policy, DHS, 245 Murray

Lane SW., Mail Stop 0445, Washington, DC 20528.

Please submit your comments by only one method. Comments received by means other than those listed above or received after the comment period has closed will not be reviewed. All comments received will be posted without change on <http://www.regulations.gov>. The <http://www.regulations.gov> Web site is the Federal e-rulemaking portal and comments posted there are available and accessible to the public. Commenters should not include personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses in their comments as such information will become viewable by the public on the <http://www.regulations.gov> Web site. It is the commenter's responsibility to safeguard his or her information. Comments submitted through <http://www.regulations.gov> will not include the commenter's email address unless the commenter chooses to include that information as part of his or her comment.

Postal delivery in Washington, DC, may be delayed due to security concerns. Therefore, DHS encourages the public to submit comments through the <http://www.regulations.gov> Web site.

*Docket:* For access to the docket to read background documents or comments received, go to the Federal eRulemaking portal at <http://www.regulations.gov>. If you need assistance to review the comments, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section below.

**FOR FURTHER INFORMATION CONTACT:** Amanda Baran, Principal Director for Immigration Policy, 202–282–8805, [Amanda.baran@hq.dhs.gov](mailto:Amanda.baran@hq.dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 302 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, Div. C, 110 Stat. 3009–546, amended section 235(b) of the Immigration and Nationality Act (“Act”), 8 U.S.C. 1225(b), to authorize what are known as “expedited removal proceedings.” Specifically, section 235(b) was amended to authorize the Attorney General (now the Secretary of

Homeland Security<sup>1</sup>) to remove, without a hearing before an immigration judge, aliens arriving in the United States who are inadmissible under sections 212(a)(6)(C) or 212(a)(7) of the Act, 8 U.S.C. 1182(a)(6)(C) and 1182(a)(7), for lack of valid documents necessary for admission or entry or for procuring or seeking to procure a visa, other immigration-related documentation, admission to the United States, or other immigration benefit by fraud or willful misrepresentation of a material fact.

Expedited removal proceedings under section 235(b) of the Act, 8 U.S.C. 1225(b), may be applied to two categories of aliens. First, expedited removal proceedings may be used for aliens who are “arriving in the United States.” Section 235(b)(1)(A)(i) of the Act, 8 U.S.C. 1225(b)(1)(A)(i). Second, the Secretary, in his or her sole and unreviewable discretion, may designate certain other aliens to whom the expedited removal provisions may be applied. Section 235(b)(1)(A)(iii), 8 U.S.C. 1225(b)(1)(A)(iii); *see* 8 CFR 235.3(b)(1)(ii).

When it created the expedited removal process, Congress also created a limited exception for certain aliens who arrived at a U.S. port of entry by aircraft. Under section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F), expedited removal “shall not apply to an alien who is a native or citizen of a country in the Western Hemisphere with whose government the United States does not have full diplomatic relations and who arrives by aircraft at a port of entry.” For many years, this exception applied to Cuban nationals due to the lack of full diplomatic relations between the United States and Cuba. DHS regulations implementing section 235(b)(1) of the Act, 8 U.S.C. 1225(b)(1), thus expressly stated that the expedited removal provisions apply to “[a]rriving aliens, as defined in 8 CFR 1.2, except for citizens of Cuba arriving at a United States port-of-entry by aircraft.” 8 CFR 235.3(b)(1)(i); *see also* 8

<sup>1</sup> Under section 1517 of title XV of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions that were transferred from the Attorney General or other Department of Justice (DOJ) official to DHS by the HSA “shall be deemed to refer to the Secretary” of Homeland Security. *See* 6 U.S.C. 557 (2003) (codifying HSA, tit. XV, sec. 1517); 6 U.S.C. 542 note; 8 U.S.C. 1551 note.



CFR 1235.3(b)(1)(i) (parallel Department of Justice (DOJ) regulations stating that the expedited removal provisions apply to “[a]rriving aliens, as defined in [8 CFR 1001.1(q)], except for citizens of Cuba arriving at a United States port-of-entry by aircraft”).<sup>2</sup>

Since that regulation was promulgated, significant changes in the relationship between the United States and Cuba have occurred. In December 2014, President Obama announced a historic opening between the United States and Cuba, as well as an approach for reestablishing diplomatic relations and adjusting regulations to facilitate greater travel, commerce, people-to-people ties, and the free flow of information to, from, and within Cuba. On July 20, 2015, the United States and Cuba formally reestablished full diplomatic relations and opened embassies in each other’s countries. In the time following the reestablishment of full diplomatic relations, the United States and Cuba have taken concrete steps towards enhancing security, building bridges between our peoples, and promoting economic prosperity for citizens of both countries. And recent migration discussions have yielded important changes that will dramatically affect travel and migration between our two countries. Among other things, Cuba has agreed to accept and facilitate the repatriation of its nationals who are ordered removed from the United States. This arrangement and other changes remain the focus of ongoing diplomatic discussions between the two countries. DHS, in consultation with the Department of State, has determined that the limitation at section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F) no longer applies with respect to Cuba.

Moreover, DHS has recently seen a significant increase in attempts by Cuban nationals to illegally enter the United States. Many of those Cuban nationals have taken a dangerous journey through Central America and Mexico; others have taken to the high seas in the dangerous attempt to cross the Straits of Florida. DHS believes this increase in attempted migration has been driven in part by the perception that there is a limited window before the United States will eliminate

favorable immigration policies for Cuban nationals.

The application of the expedited removal authorities to Cuban nationals must reflect these new realities. Accordingly, DHS is eliminating provisions in its regulations that categorically exempt Cuban nationals who arrive at a U.S. port of entry by aircraft from expedited removal proceedings under 8 CFR 235.3. Importantly, the statutory provision categorically barring the use of expedited removal for certain aliens who arrive by air no longer applies to Cuban nationals, as the United States and Cuba have reestablished full diplomatic relations. Moreover, previous U.S. policy justifications for exempting Cuban nationals from expedited removal—including Cuba’s general refusal to accept the repatriation of its nationals—are no longer valid in many respects. Finally, a categorical exception severely impairs the Government’s ability to remove unauthorized aliens encountered within the United States. For these reasons, DHS, in consultation with the Department of State, has determined that a categorical exception from expedited removal for Cuban nationals is no longer in the interests of the United States. Accordingly, as a result of this final rule, Cuban nationals will be subject to expedited removal proceedings under section 235(b) of the INA and 8 CFR 235.3 like nationals of other countries. For the same reasons, DHS is also publishing a notice in this issue of the **Federal Register** to remove the parallel exceptions for expedited removal of Cuban nationals who arrive by sea or who are encountered by an immigration officer within 100 air miles of the U.S. border.

## II. Statutory and Regulatory Requirements

### A. Administrative Procedure Act

The implementation of this rule as a final rule, with provisions for post-promulgation public comments, is based on the good cause exception found in section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(B)). Delaying the implementation of the change announced in this rule to allow pre-promulgation notice and comment would be impracticable and contrary to the public interest. Congress explicitly authorized the Secretary of Homeland Security to designate categories of aliens to whom expedited removal proceedings may be applied, and made clear that “[s]uch designation shall be in the sole and unreviewable discretion of the Secretary and may be

modified at any time.” Section 235(b)(1)(A)(iii)(I) of the Act, 8 U.S.C. 1225(b)(1)(A)(iii)(I). And this rule is necessary to remove quickly from the United States certain Cuban nationals who arrive by air at U.S. ports of entry. The ability to detain such aliens while admissibility and identity are determined and protection claims are adjudicated, as well as to quickly remove those without protection claims or claims to lawful status, is a necessity for national security and public safety.

Pre-promulgation notice and comment would undermine these interests, while endangering human life and having a potential destabilizing effect in the region. Specifically, DHS is concerned that publication of the rule as a proposed rule, which would signal a significant change in policy while permitting continuation of the exception for Cuban nationals, could lead to a surge in migration of Cuban nationals seeking to travel to and enter the United States during the period between the publication of a proposed and a final rule. Such a surge would threaten national security and public safety by diverting valuable Government resources from counterterrorism and homeland security responsibilities. A surge could also have a destabilizing effect on the region, thus weakening the security of the United States and threatening its international relations. Additionally, a surge could result in significant loss of human life. Accordingly, DHS finds that it would be impracticable and contrary to the public interest to accept pre-promulgation comments on this rule. For the same reasons, DHS also finds good cause to issue this rule without a 30-day delayed effective date requirement of the APA, see 5 U.S.C. 553(d).<sup>3</sup>

In addition, the change implemented by this rule is part of a major foreign policy initiative announced by the President, and is central to ongoing diplomatic discussions between the United States and Cuba with respect to travel and migration between the two countries. DHS, in consultation with the Department of State, has determined that eliminating the exception from expedited removal proceedings for Cuban nationals involves a foreign affairs function of the United States, 5 U.S.C. 553(a)(1), and is also exempt from the notice and comment and 30-day delayed effective date requirements of the APA on that basis. DHS is

<sup>2</sup> DOJ initially promulgated 8 CFR 235.3(b)(1)(i) as an exercise of the functions of the former Immigration and Naturalization Service (INS) and the Executive Office for Immigration Review. See 62 FR 10312 (Mar. 6, 1997). Following enactment of the HSA, 8 CFR 235.3(b)(1)(i) was transferred to DHS, and effectively duplicated in parallel DOJ regulations at 8 CFR 1235.3(b)(1)(i). See 68 FR 10349 (Mar. 5, 2003). DOJ is revising its parallel regulation by separate rulemaking in this issue of the **Federal Register**.

<sup>3</sup> In addition, in light of the lack of pre-publication notice and comment and a delayed effective date for the related notice that DHS has published in this issue of the **Federal Register**, a delay in the effective date of this regulation would be incongruous and unnecessary.

nevertheless providing the opportunity for the public to comment.

### B. Executive Orders 13563 and 12866

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

The Office of Management and Budget has not designated this rule as a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this rule.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare a regulatory flexibility analysis that describes the effect of a proposed rule on small entities when the agency is required to publish a general notice of proposed rulemaking. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people). Because this final rule is exempt from notice-and-comment rulemaking requirements under 5 U.S.C. 553, a regulatory flexibility analysis is not required.

### Regulatory Amendments

#### List of Subjects for 8 CFR Part 235

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

#### Authority and Issuance

For the reasons stated in the preamble, part 235 of title 8 of the Code of Federal Regulations is amended as set forth below:

#### 8 CFR CHAPTER I

#### PART 235—INSPECTION OF PERSONS APPLYING FOR ADMISSION

■ 1. The authority citation for part 235 continues to read:

**Authority:** 8 U.S.C. 1101 and note, 1103, 1183, 1185 (pursuant to E.O. 13323, 69 FR 241, 3 CFR, 2004 Comp., p. 278), 1201, 1224, 1225, 1226, 1228, 1365a note, 1365b, 1379, 1731–32; Title VII of Public Law 110–229; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458); Pub. L. 112–54.

■ 2. Revise § 235.3(b)(1)(i) to read as follows:

#### § 235.3 Inadmissible aliens and expedited removal.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) Arriving aliens, as defined in 8 CFR 1.2;

\* \* \* \* \*

Signed: at Washington, DC, this 11th of January 2017.

**Jeh Charles Johnson,**

*Secretary of Homeland Security.*

[FR Doc. 2017–00915 Filed 1–13–17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF JUSTICE

### Executive Office for Immigration Review

#### 8 CFR Part 1235

[AG Order No. 3817–2017; EOIR Docket No. 401]

RIN 1125–AA80

#### Eliminating Exception to Expedited Removal Authority for Cuban Nationals Arriving by Air

**AGENCY:** Executive Office for Immigration Review, Department of Justice.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This final rule revises Executive Office for Immigration Review (EOIR) regulations to eliminate the categorical exception from expedited removal proceedings for Cuban nationals who arrive in the United States at a port of entry by aircraft. This final rule conforms with a parallel Department of Homeland Security (DHS) regulation. As a result of these changes, Cuban nationals who arrive in the United States at a port of entry by aircraft will be subject to expedited removal proceedings commensurate with nationals of other countries.

**DATES:** This final rule is effective January 13, 2017. Interested persons are invited to submit written comments on this final rule on or before March 20, 2017. Comments received by mail will be considered timely if they are

postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until midnight Eastern Time at the end of that day.

**ADDRESSES:** Please submit written comments to Jean King, General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, Virginia 22041. To ensure proper handling, please reference RIN No. 1125–AA80 or EOIR Docket No. 401 on your correspondence. You may submit comments electronically or view an electronic version of this proposed rule at [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:** Jean King, General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, Virginia 22041; telephone (703) 605–1744 (not a toll-free call).

#### SUPPLEMENTARY INFORMATION:

##### I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this rule. EOIR also invites comments that relate to the economic, environmental, or federalism effects that might result from this rule. To provide the most assistance to EOIR, comments should explain the reason for any recommended change, and should include data, information, or authority that supports such recommended change.

All comments submitted for this rulemaking should include the agency name and RIN 1125–AA80 or EOIR Docket No. 401. Please note that all comments received are considered part of the public record and will be made available for public inspection at [www.regulations.gov](http://www.regulations.gov), including personally identifiable information (such as a person's name, address, or any other data that might personally identify that individual) voluntarily submitted by the commenter.

If you want to submit personally identifiable information as part of your comment, but do not want it to be posted online, you must include the phrase “PERSONALLY IDENTIFIABLE INFORMATION” in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You also must prominently identify confidential

business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on [www.regulations.gov](http://www.regulations.gov).

Personally identifiable information and confidential business information provided as set forth above will be placed in the agency's public docket file, but not posted online. To inspect the agency's public docket file in person, you must make an appointment with agency counsel. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for agency counsel's contact information.

## II. Background

This rule conforms to the rule published by DHS in this issue of the **Federal Register** that revises 8 CFR 235.3(b)(1)(i). This rule revises the parallel Department of Justice (DOJ) regulation, 8 CFR 1235.3(b)(1)(i), which states that the expedited removal provisions apply to "[a]rriving aliens, as defined in [8 CFR 1001.1(q)], except for citizens of Cuba arriving at a United States port-of-entry by aircraft".<sup>1</sup> Both the DHS rule and this rule eliminate the provisions in the Departments' respective regulations that categorically exempt Cuban nationals who arrive at a U.S. port of entry by aircraft from expedited removal proceedings. As a result of these changes, Cuban nationals who arrive in the United States at a port of entry by aircraft will be subject to expedited removal proceedings commensurate with nationals of other countries.

## III. Statutory and Regulatory Requirements

### A. Administrative Procedure Act

The implementation of this rule as a final rule, with provisions for post-promulgation public comments, is based on the good cause exception found in section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(B)). Delaying the implementation of the change announced in this rule to allow pre-promulgation notice and comment would be impracticable and contrary to the public interest. Section 235(b)(1)(A)(iii)(I) of the Immigration and Nationality Act explicitly

authorizes the Secretary of Homeland Security to designate categories of aliens to whom expedited removal proceedings may be applied, and makes clear that "[s]uch designation shall be in the sole and unreviewable discretion of the Secretary and may be modified at any time." 8 U.S.C. 1225(b)(1)(A)(iii)(I). This conforming rule is necessary to conform to the DHS rulemaking, which will allow DHS to remove quickly from the United States certain Cuban nationals who arrive by air at U.S. ports of entry. The ability to detain such aliens while admissibility and identity are determined and protection claims are adjudicated, as well as to quickly remove those without protection claims or claims to lawful status, is a necessity for national security and public safety.

Pre-promulgation notice and comment would undermine these interests, while endangering human life and having a potential destabilizing effect in the region. Specifically, the Department is concerned that publication of the rule as a proposed rule, which would signal a significant change in policy while permitting continuation of the exception for Cuban nationals, could lead to a surge in migration of Cuban nationals seeking to travel to and enter the United States during the period between the publication of a proposed and a final rule. Such a surge would threaten national security and public safety by diverting valuable Government resources from counterterrorism and homeland security responsibilities. A surge could also have a destabilizing effect on the region, thus weakening the security of the United States and threatening its international relations. Additionally, a surge could result in significant loss of human life.

Accordingly, DOJ finds that it would be impracticable and contrary to the public interest to accept pre-promulgation comments on this rule. For the same reasons, DOJ also finds good cause to issue this rule without a 30-day delayed effective date requirement of the APA, *see* 5 U.S.C. 553(d).<sup>2</sup>

In addition, the change implemented by this rule is part of a major foreign policy initiative announced by the President, and is central to ongoing diplomatic discussions between the United States and Cuba with respect to travel and migration between the two countries. DOJ, in consultation with the

Department of State, has determined that eliminating the exception from expedited removal proceedings for Cuban nationals involves a foreign affairs function of the United States, 5 U.S.C. 553(a)(1), and is also exempt from the notice and comment and 30-day delayed effective date requirements of the APA on that basis. DOJ is nevertheless providing the opportunity for the public to provide comments.

### B. Executive Orders 13563 and 12866

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

The Office of Management and Budget has not designated this rule as a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this rule.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare a regulatory flexibility analysis that describes the effect of a proposed rule on small entities when the agency is required to publish a general notice of proposed rulemaking. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people). Because this final rule is exempt from notice-and-comment rulemaking requirements under 5 U.S.C. 553, a regulatory flexibility analysis is not required.

### D. Unfunded Mandates Reform Act of 1995

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

<sup>1</sup> DOJ initially promulgated 8 CFR 235.3(b)(1)(i) as an exercise of the functions of the former Immigration and Naturalization Service (INS) and the Executive Office for Immigration Review. *See* 62 FR 10312 (Mar. 6, 1997). Following enactment of the HSA, 8 CFR 235.3(b)(1)(i) was transferred to DHS, and effectively duplicated in parallel DOJ regulations at 8 CFR 1235.3(b)(1)(i). *See* 68 FR 10349 (Mar. 5, 2003).

<sup>2</sup> In addition, in light of the lack of pre-publication notice-and-comment and a delayed effective date for the related notice that DHS has published in this issue of the **Federal Register**, a delay in the effective date of this regulation would be incongruous and unnecessary.

of the Unfunded Mandates Reform Act of 1995.

#### E. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996. See 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

#### F. Executive Order 13132: Federalism

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

#### G. Executive Order 12988: Civil Justice Reform

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

#### H. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this rule because there are no new or revised recordkeeping or reporting requirements.

#### List of Subjects in 8 CFR Part 1235

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, part 1235 of title 8 of the Code of Federal Regulations is amended as follows:

#### PART 1235—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

■ 1. The authority citation for part 1235 continues to read:

**Authority:** 8 U.S.C. 1101 and note, 1103, 1183, 1185 (pursuant to E.O. 13323, 69 FR 241, 3 CFR, 2003 Comp., p. 278), 1201, 1224,

1225, 1226, 1228, 1365a note, 1379, 1731-32; Title VII of Public Law 110-229; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108-458).

■ 2. Revise § 1235.3(b)(1)(i) to read as follows:

#### § 1235.3 Inadmissible aliens and expedited removal.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) Arriving aliens, as defined in § 1001.1(q) of this chapter;

\* \* \* \* \*

Dated: January 11, 2017.

**Loretta E. Lynch,**

*Attorney General.*

[FR Doc. 2017-00902 Filed 1-13-17; 8:45 am]

**BILLING CODE 4410-30-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-9110; Directorate Identifier 2015-NM-196-AD; Amendment 39-18773; AD 2017-01-06]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Airplanes

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Airbus Model A319-115, A319-132, A320-214, A320-232, A321-211, A321-213, and A321-231 airplanes. This AD was prompted by a report of certain tie rod assemblies installed on the hinged fairing assembly of the main landing gear (MLG) with no cadmium plating on the rod end threads. This AD requires inspection and replacement of certain tie rod assemblies installed on the hinged fairing assembly of the MLG. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective February 21, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 21, 2017.

**ADDRESSES:** For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com);

Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9110.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9110; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

#### FOR FURTHER INFORMATION CONTACT:

Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

#### SUPPLEMENTARY INFORMATION:

#### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A319-115, A319-132, A320-214, A320-232, A321-211, A321-213, and A321-231 airplanes. The NPRM published in the **Federal Register** on September 19, 2016 (81 FR 64083).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015-0234, dated December 8, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A319-115, A319-132, A320-214, A320-232, A321-211, A321-213, and A321-231 airplanes. The MCAI states:

A production quality issue was identified concerning tie rod assemblies, having Part Number (P/N) starting with D52840212000 or D52840212002, which are installed on the main landing gear (MLG) hinged fairing assembly. This quality issue affects the cadmium plating surface treatment which

was inadvertently omitted from the rod end threads of the assembly. The absence of cadmium plating reduces the corrosion protection scheme.

This condition, if not detected and corrected, could lead to galvanic corrosion of the tie rod end threads, possibly resulting in rod end failure, loss of a MLG door, and consequent injury to persons on ground.

To address this unsafe condition, Airbus identified the affected [manufacturer serial number] MSN and issued [service bulletin] SB A320-52-1167 to provide inspection instructions.

For the reason described above, this [EASA] AD requires a one-time inspection of the affected MLG hinged fairing tie rod assemblies [for the presence of cadmium plating], and, depending on findings, replacement of the affected tie rod assembly.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9110.

**Comments**

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

**Conclusion**

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Related Service Information Under 14 CFR Part 51**

Airbus has issued Service Bulletin A320-52-1167, dated August 6, 2015. The service information describes procedures for a detailed inspection for the presence of cadmium plating on tie rod assemblies having certain part numbers, and procedures for replacement of tie rod assemblies with no cadmium plating on the rod end threads. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

**Costs of Compliance**

We estimate that this AD affects 20 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection .....	2 work-hours × \$85 per hour = \$170 .....	\$0	\$170	\$3,400

We estimate the following costs to do any necessary replacements that will be

required based on the results of the inspection. We have no way of

determining the number of airplanes that might need these replacements:

**ON-CONDITION COSTS**

Action	Labor cost	Parts cost	Cost per product
Replacement .....	13 work-hours × \$85 per hour = \$1,105 .....	Not available .....	\$1,105

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all available costs in our cost estimate.

**Authority for This Rulemaking**

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

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations

for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

**Regulatory Findings**

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2017-01-06 Airbus:** Amendment 39-18773; Docket No. FAA-2016-9110; Directorate Identifier 2015-NM-196-AD.

#### (a) Effective Date

This AD is effective February 21, 2017.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Airbus Model A319-115, A319-132, A320-214, A320-232, A321-211, A321-213, and A321-231 airplanes, certificated in any category, as identified in Airbus Service Bulletin A320-52-1167, dated August 6, 2015.

#### (d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

#### (e) Reason

This AD was prompted by a report of certain tie rod assemblies installed on the hinged fairing assembly of the main landing gear (MLG) with no cadmium plating on the rod end threads. We are issuing this AD to detect and correct the absence of cadmium plating on the rod end threads of the tie rod assemblies. The absence of cadmium plating could lead to galvanic corrosion of the tie rod end threads, resulting in rod end failure, loss of a MLG door, and consequent damage to the airplane.

#### (f) Compliance

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

#### (g) Inspection and Corrective Action

Within 80 months after the airplane's first flight, do a detailed inspection of each tie rod assembly having a part number (P/N) D52840212000 or D52840212002 at the MLG hinged fairing for the presence of cadmium plating (gold colored threads), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-52-1167, dated August 6, 2015. If during the inspection any tie rod assembly is found that does not have cadmium plating, before further flight, replace the tie rod assembly with a serviceable part having the same part number and cadmium plating, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-52-1167, dated August 6, 2015.

#### (h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International

Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

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

#### (i) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015-0234, dated December 8, 2015, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-9110.

#### (j) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320-52-1167, dated August 6, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France;

telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on December 23, 2016.

**Thomas Groves,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016-31961 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-7419; Directorate Identifier 2015-NM-189-AD; Amendment 39-18769; AD 2017-01-02]

RIN 2120-AA64

#### Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787-8 and 787-9 airplanes. This AD was prompted by a report that some inboard and outboard trailing edge flap rotary actuators may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. This AD requires inspecting the trailing edge flap rotary actuator, and replacing the rotary actuator or doing related investigative and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective February 21, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 21, 2017.

**ADDRESSES:** For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC

110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-7419.

**Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-7419; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Fnu Winarto, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6659; fax: 425-917-6590; email: [fnu.winarto@faa.gov](mailto:fnu.winarto@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would

apply to certain The Boeing Company Model 787-8 and 787-9 airplanes. The NPRM published in the **Federal Register** on July 12, 2016 (81 FR 45070) (“the NPRM”). The NPRM was prompted by a report that some inboard and outboard trailing edge flap rotary actuators may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. The NPRM proposed to require an inspection of the inboard and outboard flap trailing edge rotary actuator for any discrepant rotary actuator. For discrepant rotary actuators, the NPRM proposed to require replacing the rotary actuator, or alternatively, determining the flight cycles on the rotary actuator, and doing related investigative and corrective actions if necessary. We are issuing this AD to detect and replace rotary actuators having incorrect assembly, which could cause accelerated unit wear that will eventually reduce braking performance. This degradation could lead to loss of no-back brake function and reduced controllability of the airplane.

**Comments**

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response. Boeing stated that it supported the NPRM. United Airlines (UAL) stated that it supported the compliance time in the NPRM.

**Request for the Manufacturer To Re-Evaluate Its Warranty Policy**

UAL requested that Boeing re-evaluate its warranty policy. UAL stated that an incorrect stack sequence occurred during the manufacturing process and that operators should not be penalized for having to perform the test and replacement of the rotary actuators.

We partially agree with the request. We agree that this is a manufacturing issue. However, we have not revised this final rule in this regard because we do not regulate Boeing’s warranty policy.

**Conclusion**

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Related Service Information Under 1 CFR Part 51**

We reviewed Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015. The service information describes procedures for an inspection of the inboard and outboard flap rotary actuator for any discrepant rotary actuator, and procedures for replacing the rotary actuator, or determining the flight cycles on the rotary actuator and doing applicable related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

**Costs of Compliance**

We estimate that this AD affects 5 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection .....	1 work-hour × \$85 per hour = \$85 .....	\$0	\$85	\$425

We estimate the following costs to do any necessary on-condition actions that

will be required based on the results of the inspection. We have no way of

determining the number of aircraft that might need this replacement:

**ON-CONDITION COSTS**

Action	Labor cost	Parts cost	Cost per product
Check to determine flight cycles on the rotary actuator.	1 work-hour × \$85 per hour = \$85 .....	\$0	\$85
Functional test .....	2 work-hours × \$85 per hour = \$170 .....	\$0	\$170
Replacement .....	2 work-hours × \$85 per hour = \$170 .....	\$0	\$170



### Authority for This Rulemaking

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

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

### Regulatory Findings

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

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

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2017-01-02 The Boeing Company:**  
Amendment 39-18769; Docket No. FAA-2016-7419; Directorate Identifier 2015-NM-189-AD.

#### (a) Effective Date

This AD is effective February 21, 2017.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 787-8 and 787-9 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015.

#### (d) Subject

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

#### (e) Unsafe Condition

This AD was prompted by a report that some inboard and outboard trailing edge flap rotary actuators may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. We are issuing this AD to detect and replace rotary actuators having incorrect assembly, which could cause accelerated unit wear that will eventually reduce braking performance. This degradation could lead to loss of no-back brake function and reduced controllability of the airplane.

#### (f) Compliance

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

#### (g) Inspection and Other Actions

Within 60 months after the effective date of this AD, do an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015. If any discrepant rotary actuator is found, within 60 months after the effective date of this AD, do the actions specified in paragraph (g)(1) or (g)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015.

(1) Replace the discrepant rotary actuator.

(2) Check the maintenance records to determine the flight cycles of each discrepant rotary actuator and, within 60 months after the effective date of this AD, do all applicable related investigative and corrective actions.

#### (h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19,

send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

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

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

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(4)(i) and (h)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled "RC Exempt," then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

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

#### (i) Related Information

For more information about this AD, contact Fnu Winarto, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6659; fax: 425-917-6590; email: [fnu.winarto@faa.gov](mailto:fnu.winarto@faa.gov).

#### (j) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin B787-81205-SB270032-00, Issue 001, dated November 3, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; Internet <https://www.myboeingfleet.com>.



(4) You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425 227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on December 27, 2016.

**Jeffrey E. Duven,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016-31959 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2013-0797; Directorate Identifier 2013-NM-007-AD; Amendment 39-18776; AD 2017-01-09]

RIN 2120-AA64

#### Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 767-300 and 767-300F series airplanes. This AD was prompted by reports of malfunctions in the flight deck display units, which resulted in blanking, blurring, or loss of color on the display. This AD requires modification and installation of components in the main equipment center. For certain other airplanes this AD requires modification, replacement, and installation of flight deck air relief system (FDARS) components. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective February 21, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 21, 2017.

**ADDRESSES:** For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone: 562-797-1717; Internet:

<https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2013-0797.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2013-0797; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

#### FOR FURTHER INFORMATION CONTACT:

Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Controls Branch, ANM-150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6596; fax: 425-917-6590; email: [francis.smith@faa.gov](mailto:francis.smith@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767-300 and 767-300F series airplanes. The SNPRM published in the **Federal Register** on May 27, 2016 (81 FR 33612) (“the SNPRM”). We preceded the SNPRM with a notice of proposed rulemaking (NPRM) that published in the **Federal Register** on September 25, 2013 (78 FR 58970) (“the NPRM”). The NPRM proposed to require modification and installation of components in the main equipment center. For certain other airplanes, the NPRM proposed to require modification, replacement, and installation of FDARS components. The NPRM was prompted by reports of malfunctions in the flight deck display units, which resulted in blanking, blurring, or loss of color on the display. The SNPRM proposed to revise the applicability, add certain modifications,

and clarify certain requirements. We are issuing this AD to prevent malfunctions of the flight deck display units, which could affect the ability of the flight crew to read the displays for airplane attitude, altitude, or airspeed, and consequently reduce the ability of the flight crew to maintain control of the airplane.

#### Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the SNPRM and the FAA’s response to each comment.

#### Support for the SNPRM

The Air Line Pilots Association, International supported the intent of the SNPRM.

#### Effect of Winglets on Accomplishment of the Specified Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate (STC) ST01920SE does not affect the accomplishment of the manufacturer’s service instructions.

We agree with the commenter that STC ST01920SE does not affect the accomplishment of the manufacturer’s service instructions. Therefore, the installation of STC ST01920SE does not affect the ability to accomplish the actions required by this AD. We have not changed this final rule in this regard.

#### Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

#### Related Service Information Under 14 CFR Part 51

We reviewed the following service information.

- Boeing Service Bulletin 767-21-0235, dated October 8, 2009; and Revision 1, dated July 29, 2011 (“SB 767-21-0235, R1”). The service information describes procedures for a relay installation and related wiring changes (which change (modify) the 3-way valve control logic for the cooling system for the flight deck display equipment on freighter airplanes).

- Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010 (“SB 767–27–0244, R1”). The service information describes procedures for changing (modifying) the 3-way valve control logic and installing a cooling system for the flight deck display equipment.
- Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013 (“ASB 767–21A0245, R2”); and Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013 (“ASB 767–21A0247, R1”). The service information describes procedures for changing (modifying) the 3-way valve control logic and main cargo air distribution system (MCADS), and installing an FDARS. These

documents are distinct since they apply to different airplane models.

- Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012. The service information describes procedures for replacing the existing duct, installing an FDARS, changing (modifying) the 3-way valve control logic, and installing a new altitude switch and pitot tube.
- Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013. The service information describes procedures for replacing the duct with a new duct; installing an FDARS (including the installation of mounting brackets, ducts, orifice, outlet valve, and screen); and activating the 3-way valve

logic (including modification of the associated wiring and related actions).

- Boeing Service Bulletin 767–31–0073, dated October 12, 1995. The service information describes procedures for installing a maintenance data selection system for the engine indication and crew alerting system.

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

**Costs of Compliance**

We estimate that this AD affects 52 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3-way valve control logic and MCADS change and FDARS installation (ASB 767–21A0247, R1).	46 work-hours × \$85 per hour = \$3,910.	\$21,865 .....	\$25,775 .....	\$1,185,650 (46 airplanes).
3-way valve control logic and MCADS change and FDARS installation (ASB 767–21A0245, R2).	64 work-hours × \$85 per hour = \$5,440.	\$18,315 .....	\$23,755 .....	\$47,510 (2 airplanes).
3-way valve logic change and installation of FDARS components (Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012).	76 work-hours × \$85 per hour = \$6,460.	\$55,663 .....	\$62,123 .....	\$248,492 (4 airplanes).
Change (modify) the 3-way valve control logic change and installation of a flight deck display equipment cooling system (SB 767–27–0244, R1).	33 work-hours × \$85 per hour = \$2,805.	\$0 .....	\$2,805 .....	\$8,415 (3 airplanes).
Relay installation and related wiring changes (Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or SB 767–21–0235, R1).	Up to 10 work-hours × \$85 per hour = up to \$850.	Up to \$955 .....	Up to \$1,805 .....	Up to \$88,445 (49 airplanes).
Activation of 3-way valve logic change and installation of FDARS (Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013).	51 work-hours × \$85 per hour = \$4,335.	\$16,338 .....	\$20,673 .....	(0 airplanes).
Installation of engine indication and crew alerting system maintenance data selection system (Boeing Service Bulletin 767–31–0073, dated October 12, 1995).	Up to 13 work-hours × \$85 per hour = \$1,105.	Up to \$3,535 .....	Up to \$4,640 .....	Up to \$13,920 (3 airplanes).

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

#### 2017-01-09 The Boeing Company:

Amendment 39-18776; Docket No. FAA-2013-0797; Directorate Identifier 2013-NM-007-AD.

#### (a) Effective Date

This AD is effective February 21, 2017.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 767-300 and 767-300F series airplanes, certificated in any category; as identified in the service information specified in paragraphs (c)(1) through (c)(5) of this AD. This AD does not apply to The Boeing Company Model 767-300 (passenger) series airplanes.

(1) Boeing Service Bulletin 767-21-0244, Revision 1, dated March 8, 2010 (“SB 767-27-0244, R1”).

(2) Boeing Alert Service Bulletin 767-21A0245, Revision 2, dated September 27, 2013 (“ASB 767-21A0245, R2”).

(3) Boeing Alert Service Bulletin 767-21A0247, Revision 1, dated April 9, 2013 (“ASB 767-21A0247, R1”).

(4) Boeing Alert Service Bulletin 767-21A0253, dated October 12, 2012.

(5) Boeing Alert Service Bulletin 767-21A0254, dated June 7, 2013.

#### (d) Subject

Air Transport Association (ATA) of America Code 21, Air Conditioning.

#### (e) Unsafe Condition

This AD was prompted by reports of malfunctions in the flight deck display units, which resulted in blanking, blurring, or loss of color on the display. We are issuing this

AD to prevent malfunctions of the flight deck display units, which could affect the ability of the flight crew to read the displays for airplane attitude, altitude, or airspeed, and consequently reduce the ability of the flight crew to maintain control of the airplane.

#### (f) Compliance

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

#### (g) Installation of Flight Deck Air Relief System (FDARS) and 3-Way Valve Logic Change or Activation

(1) For Model 767-300F series airplanes, as identified in Boeing Alert Service Bulletin 767-21A0253, dated October 12, 2012: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, replace the existing duct with a new duct; install an FDARS (including the installation of mounting brackets, ducts, orifice, outlet valve, and screen); change the 3-way valve logic (including modification of the associated wiring and related actions); and install a new altitude switch and pitot tube; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767-21A0253, dated October 12, 2012.

(2) For Model 767-300F series airplanes, as identified in Boeing Alert Service Bulletin 767-21A0254, dated June 7, 2013: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, replace the duct with a new duct; install an FDARS (including the installation of mounting brackets, ducts, orifice, outlet valve, and screen); and activate the 3-way valve logic (including modification of the associated wiring and related actions); in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767-21A0254, dated June 7, 2013.

#### (h) Installation of FDARS and a 3-Way Valve Control Logic and Main Cargo Air Distribution System Change

(1) For Model 767-300F series airplanes, as identified in ASB 767-21A0245, R2: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, change (modify) the 3-way valve control logic and main cargo air distribution system (MCADS), and install an FDARS, in accordance with the Accomplishment Instruction of ASB 767-21A0245, R2, except as provided by paragraph (j) of this AD.

(2) For Model 767-300F series airplanes, as identified in ASB 767-21A0247, R1: Within 72 months after the effective date of this AD, change (modify) the 3-way valve control logic and MCADS, and install an FDARS, in accordance with the Accomplishment Instructions of ASB 767-21A0247, R1.

#### (i) Installation of a Flight Deck Display Equipment Cooling System and a 3-Way Valve Logic Change

For Model 767-300 series airplanes that have been converted by Boeing to Model 767-300BCF (Boeing Converted Freighter) airplanes, as identified in SB 767-27-0244,

R1: Within 72 months after the effective date of this AD, change (modify) the 3-way valve control logic and install a flight deck display equipment cooling system, in accordance with the Accomplishment Instructions of SB 767-27-0244, R1.

#### (j) Exception to Paragraph (h)(1) of this AD

For Model 767-300F series airplanes, as identified in ASB 767-21A0245, R2: If the 3 way valve control logic change (modification) specified in Boeing Service Bulletin 767-21-0235, dated October 8, 2009; or Revision 1, dated July 29, 2011 (“SB 767-21-0235, R1”); is done prior to or concurrent with the actions required by paragraph (h)(1) of this AD, operators need to do only the functional test, FDARS installation, and flex duct change, in accordance with the Accomplishment Instructions of ASB 767-21A0245, R2. Operators do not need to do the other actions specified in the Accomplishment Instructions of ASB 767-21A0245, R2, if the actions in the Accomplishment Instructions of Boeing Service Bulletin 767-21-0235, dated October 8, 2009; or SB 767-21-0235, R1; are done concurrently. If the functional test fails, before further flight, do corrective actions that are approved in accordance with the procedures specified in paragraph (l) of this AD.

#### (k) Concurrent Requirements

(1) For Groups 1 and 3 airplanes, as identified in ASB 767-21A0245, R2: Prior to or concurrently with accomplishing the requirements of paragraph (h)(1) of this AD, do the relay installation and related wiring changes specified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 767-21-0235, dated October 8, 2009; or SB 767-21-0235, R1.

(2) For Group 1 airplanes, as identified in ASB 767-21A0247, R1: Prior to or concurrently with accomplishing the requirements of paragraph (h)(2) of this AD, do the relay installation and related wiring changes specified in the Accomplishment Instructions of Boeing Service Bulletin 767-21-0235, dated October 8, 2009; or SB 767-21-0235, R1.

(3) For Model 767-300 series airplanes that have been converted by Boeing to Model 767-300BCF airplanes, as identified in SB 767-27-0244, R1: Prior to or concurrently with accomplishing the requirements of paragraph (i) of this AD, do all the actions (installation) specified in the Accomplishment Instructions of Boeing Service Bulletin 767-31-0073, dated October 12, 1995.

#### (l) Alternative Methods of Compliance (AMOCs)

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

emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

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

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

#### (m) Related Information

For more information about this AD, contact Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Controls Branch, ANM-150S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6596; fax: 425-917-6590; email: [francis.smith@faa.gov](mailto:francis.smith@faa.gov).

#### (n) Material Incorporated by Reference

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

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

(i) Boeing Service Bulletin 767-21-0235, dated October 8, 2009.

(ii) Boeing Service Bulletin 767-21-0235, Revision 1, dated July 29, 2011.

(iii) Boeing Service Bulletin 767-21-0244, Revision 1, dated March 8, 2010.

(iv) Boeing Alert Service Bulletin 767-21A0245, Revision 2, dated September 27, 2013.

(v) Boeing Alert Service Bulletin 767-21A0247, Revision 1, dated April 9, 2013.

(vi) Boeing Alert Service Bulletin 767-21A0253, dated October 12, 2012.

(vii) Boeing Alert Service Bulletin 767-21A0254, dated June 7, 2013.

(viii) Boeing Service Bulletin 767-31-0073, dated October 12, 1995.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone: 562-797-1717; Internet: <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on December 30, 2016.

**John P. Piccola, Jr.,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2017-00115 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 742

[Docket No. 160901810-6810-01]

RIN 0694-AH10

#### Revisions to Sudan Licensing Policy

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Final rule.

**SUMMARY:** This rule revises the policy of review for applications for licenses to export or reexport to Sudan certain items that are intended to ensure the safety of civil aviation or the safe operation of fixed-wing, commercial passenger aircraft. Such applications will now be reviewed under a general policy of approval rather than a general policy of denial.

This rule also revises the review policy from a general policy of denial to a general policy of approval for applications for licenses to export or reexport to Sudan certain items for use to inspect, design, construct, operate, improve, maintain, repair, overhaul or refurbish railroads in Sudan. This rule does not create any new license requirements or remove any existing license requirements for exports or reexports to Sudan. BIS is making these licensing policy changes in connection with ongoing U.S.-Sudan bilateral engagement, and with the aim of enhancing the safety of Sudan's civil aviation and improving the country's railroads. This action takes into account the United States' goals to improve regional peace and security.

This rule also removes two instances of "contract sanctity dates" pertaining to the export and reexport of certain items to Sudan from the EAR that currently serve no practical purpose.

BIS is taking these actions in coordination with the Department of the Treasury's Office of Foreign Assets Control (OFAC), which is amending the Sudanese Sanctions Regulations.

**DATES:** *Effective Date:* January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Foreign Policy Division, Bureau of Industry and Security, Phone: (202) 482-4252.

#### SUPPLEMENTARY INFORMATION:

##### Background

Pursuant to § 742.10 of the Export Administration Regulations (EAR), in keeping with Sudan's designation as a state sponsor of terrorism, persons must obtain a license to export or reexport to Sudan all aircraft controlled on the Commerce Control List (Supp. No. 1 to part 774 of the EAR) (CCL) and to export related parts and components that are controlled on the CCL. Prior to the publication of this rule, the EAR imposed a general policy of denial on license applications for such exports or reexports to all end-users and for all end uses in Sudan. This rule revises the licensing policy to a general policy of approval for parts, components, materials, equipment, and technology that are controlled on the CCL only for anti-terrorism reasons and that are intended to ensure the safety of civil aviation or the safe operation of fixed-wing, commercial passenger aircraft.

Applications to export or reexport to Sudan complete aircraft and applications to export or reexport to Sudan aircraft-related items that are controlled for anti-terrorism reasons and one or more additional reasons (for example, missile technology reasons) will continue to be reviewed under a general policy of denial to all end users.

This rule also revises the general policy of denial to a general policy of approval for license applications to export or reexport to Sudan items controlled on the CCL only for anti-terrorism reasons that will be used to inspect, design, construct, operate, improve, maintain, repair, overhaul or refurbish railroads in Sudan.

With respect to both aircraft related-items and railroad-related items, the general policies of approval set forth in this rule apply only to exports and reexports to Sudan for civil uses by non-sensitive end-users within Sudan. Sensitive end users, who are not eligible for these policies, include Sudan's military, police, and/or intelligence services and persons that are owned by or are part of or are operated or controlled by those services. Additionally, license applications for the export or reexport of items that would substantially benefit such sensitive end users will generally be denied. To implement these policies, this rule revises § 742.10(b)(3) of the EAR, which sets forth exceptions to the general policies of denial that apply to most license applications to export or reexport to Sudan.

In conjunction with this rule, the Department of the Treasury's Office of Foreign Assets Control (OFAC) is

amending the Sudanese Sanctions Regulations, 31 CFR part 538, to add a new general license that authorizes all transactions prohibited by those regulations and by Executive Orders 13067 and 13412. Under OFAC's new general license, newly-authorized transactions include the processing of transactions involving persons in Sudan; the importation of goods and services from Sudan; the exportation of goods, technology, and services to Sudan; and transactions involving property in which the Government of Sudan has an interest. Persons interested in exporting or reexporting to Sudan goods and technology that are subject to the EAR, including items related to railroads or the safety of civil aviation or safe operation of fixed-wing commercial passenger aircraft, pursuant to OFAC's new general license should consult BIS regarding any licensing obligations they may have under the EAR.

BIS will continue to evaluate license applications in light of section 6(j) of the Export Administration Act of 1979 (EAA), as continued in effect under the International Emergency Economic Powers Act, and any other relevant legal requirements.

This rule also removes and reserves paragraphs (c)(6)(iii) and (c)(10)(iii) of Supplement No. 2 to part 742, which state licensing policy and contract sanctity dates for aircraft, and cryptographic and cryptologic equipment, respectively. The licensing policies for these commodities are stated in paragraphs (b)(1)(iv) and (b)(1)(v) of § 742.10 and need not be repeated in Supplement No. 2. Moreover, as a consequence of this rule, which revises licensing policy for certain aircraft-related items and railroad-related items, the latter category potentially including cryptographic and cryptologic equipment, paragraphs (c)(6)(iii) and (c)(10)(iii)'s statements of a general policy of denial for all end-users in Sudan is no longer accurate. Additionally, the recitation of contract sanctity dates in Supplement No. 2 does not serve a practical purpose. The term "contract sanctity date" draws on section 6(p) of the EAA. That section constrains BIS's ability to limit exports and reexports in performance of contracts entered into prior to the date of imposition of export controls. The references to the contract sanctity dates in the supplement do not limit or otherwise affect the right of any license applicant to assert that the provisions of section 6(p) of the EAA apply to the license application that it is submitting. The identified dates are also long outdated, with March 21, 2003, the most

recent contract sanctity date that this rule removes from Supplement No. 2 to part 742.

#### Export Administration Act of 1979

Although the Export Administration Act of 1979 expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

#### Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined not to be significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number. This rule involves a collection of information approved under OMB control number 0694-0088—Simplified Network Application Processing+ System (SNAP+) and the Multipurpose Export License Application, which carries an annual estimated burden of 31,833 hours. BIS believes that this rule will have no material impact on that burden. To the extent that it has any impact, BIS believes that the benefits of this rule justify any additional burden it creates. This rule does not impose any new license requirements; in fact, it creates more favorable license application review policies for exports and

reexports to Sudan. These more favorable policies might increase the number of license applications submitted to BIS because applicants might be more optimistic about obtaining approval. However, the benefit to license applicants in the form of greater likelihood of approval justifies any additional burden. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget, by email at [jseehra@omb.eop.gov](mailto:jseehra@omb.eop.gov) or by fax to (202) 395-7285 and to Sheila Quarterman at [sheila.quarterman@bis.doc.gov](mailto:sheila.quarterman@bis.doc.gov).

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking and the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (*see* 5 U.S.C. 553(a)(1)). BIS is making these licensing policy changes in connection with ongoing U.S.-Sudan bilateral engagement, and with the aim of enhancing the safety of Sudan's civil aviation and improving its railroads. This decision takes into account our goals to improve regional peace and security. A delay in effective date would undermine progress in that bilateral engagement adversely impacting the U.S. Government's foreign policy goals of improving regional peace and security.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553, or by any other law, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

#### List of Subjects in 15 CFR Part 742

Exports, Terrorism.

For the reasons set forth in the preamble, part 742 of the Export Administration Regulations (15 CFR parts 730-774) is amended as follows:

#### PART 742—[AMENDED]

■ 1. The authority citation for 15 CFR part 742 continues to read as follows:

**Authority:** 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*;

42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

■ 2. Section 742.10 is amended by:

■ a. Adding a paragraph heading to paragraph (b)(1) introductory text;

■ b. Revising the first sentence of paragraph (b)(1)(iv);

■ c. Adding a paragraph heading to paragraph (b)(2); and

■ d. Revising paragraph (b)(3).

The additions and revisions read as follows:

**§ 742.10 Anti-terrorism: Sudan.**

\* \* \* \* \*

(b) \* \* \*

(1) *General policy of denial.* \* \* \*

\* \* \* \* \*

(iv) Except as provided in paragraph (b)(3)(ii) of this section, all aircraft (powered and unpowered), helicopters, engines and related spare parts and components. \* \* \*

\* \* \* \* \*

(2) *Military end-user and end-use policy.* \* \* \*

(3) *Other licensing policies.* The licensing policies set forth in this paragraph apply notwithstanding the provisions of paragraphs (b)(1) and (b)(2) of this section.

(i) *Case-by-case review policy.* Applications to export or reexport to Sudan will be considered on a case-by-case basis in the four situations described in paragraphs (b)(3)(i)(A) through (D) of this section.

(A) The transaction involves the reexport to Sudan of items where Sudan was not the intended ultimate destination at the time of original export from the United States, provided that the export from the United States occurred prior to the applicable contract sanctity date.

(B) The U.S. content of foreign-produced commodities is 20% or less by value.

(C) The commodities are medical items.

(D) The items are telecommunications equipment and associated computers, software and technology for civil end use, including items useful for the development of civil telecommunications network infrastructure.

*Note to paragraph (b)(3)(i).* Applicants seeking approval of their

license applications pursuant to this paragraph must include with their applications documentation demonstrating how their proposed transaction is consistent with one or more of the four situations described in this paragraph.

(ii) *General policy of approval.*

Applications to export or reexport to Sudan the following for civil uses by non-sensitive end-users within Sudan will be reviewed with a general policy of approval.

(A) Parts, components, materials, equipment, and technology that are controlled on the Commerce Control List (Supp. No. 1 to part 774 of the EAR) only for anti-terrorism reasons that are intended to ensure the safety of civil aviation or the safe operation of fixed-wing commercial passenger aircraft.

(B) Items controlled on the Commerce Control List (Supp. No. 1 to part 774 of the EAR) only for anti-terrorism reasons that will be used to inspect, design, construct, operate, improve, maintain, repair, overhaul or refurbish railroads in Sudan.

*Note to paragraph (b)(3)(ii).*

Applications will generally be denied for exports or reexports that would substantially benefit a sensitive end user. Sensitive end users include Sudan's military, police, and intelligence services and persons that are owned by or are part of or operated or controlled by those services.

\* \* \* \* \*

**Supplement No. 2 to Part 742 [Amended]**

■ 3. In Supplement No. 2 to part 742, remove and reserve paragraphs (c)(6)(iii) and (c)(10)(iii).

Dated: January 4, 2017.

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

[FR Doc. 2017–00836 Filed 1–13–17; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF JUSTICE**

**28 CFR Part 31**

[Docket No.: OJP (OJJDP) 1719]

**RIN 1121–AA83**

**Juvenile Justice and Delinquency Prevention Act Formula Grant Program**

**AGENCY:** Office of Justice Programs, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Office of Juvenile Justice and Delinquency Prevention (“OJJDP”)

of the U.S. Department of Justice’s Office of Justice Programs (“OJP”), publishes this partial final rule to amend portions of the formula grant program (“Formula Grant Program”) regulation to reflect changes in OJJDP policy.

**DATES:** *Effective Date:* This rule is effective February 16, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Gregory Thompson, Senior Advisor, Office of Juvenile Justice and Delinquency Prevention, at 202–307–5911.

**SUPPLEMENTARY INFORMATION:** The OJJDP Formula Grant Program is authorized by the Juvenile Justice and Delinquency Prevention Act (“JJDA”). The JJDA authorizes OJJDP to provide an annual grant to each State to improve its juvenile justice system and to support juvenile delinquency prevention programs. OJJDP published a notice of proposed rulemaking on August 8, 2016, 81 FR 52377, that proposed to revise the entirety of the Formula Grant Program regulation.

OJJDP is finalizing some, but not all, aspects of the proposed rule here. For several provisions, OJJDP has addressed the comments received and is amending the current Formula Grant Program regulation through this partial final rule. For other provisions included in the proposed rule, OJJDP received voluminous comments that will require additional time for OJJDP to consider them thoughtfully. OJJDP anticipates publishing a final rule in the future addressing the remainder of the proposed changes that are not addressed in this partial final rule.

**I. Executive Summary**

*A. Purpose of the Regulatory Action*

The JJDA authorizes annual formula grants to be made to States to improve their juvenile justice systems and to support juvenile delinquency prevention programs.<sup>1</sup> See 42 U.S.C. 5631(a). OJJDP promulgates this rule pursuant to the rulemaking authority granted to the OJJDP Administrator (the Administrator) by 42 U.S.C. 5611(b).

*B. Summary of the Major Provisions of the Partial Final Rule*

This rule amends the Formula Grant Program regulation in the following respects: (1) It replaces 28 CFR 31.303(f)(6), which provides standards for determining compliance with the

<sup>1</sup> Pursuant to 42 U.S.C. 5603(7), “the term ‘State’ includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of Northern Mariana Islands.”

core requirements found at 42 U.S.C. 5633(a)(11), the “deinstitutionalization of status offenders” (DSO); 42 U.S.C. 5633(a)(12), “separation”; and 42 U.S.C. 5633(a)(13), “jail removal”; (2) it provides a definition for the term “detain or confine,” clarifying that the term refers to both the secure detention and non-secure detention of juveniles; (3) it changes the deadline to February 28th for States to report their compliance monitoring data for the previous federal fiscal year and provides that the Administrator may, for good cause, grant a State’s request for an extension of the February 28th reporting deadline to March 31st; (4) it requires that States provide compliance data for 85% of facilities that are required to report on compliance with the DSO, separation, and jail removal requirements; and (5) it adds a requirement that States provide a full twelve months’ worth of compliance data for each reporting period.

### C. Cost and Benefits

As noted in the preamble to the Notice of Proposed Rulemaking, it is difficult to quantify the financial costs to States of the increased monitoring and reporting requirements, and OJJDP did not receive any comments from States indicating what those increased costs might be. OJJDP expects, however, that those costs will be considerably lower under this partial final rule than they would have been under the proposed rule. For example, under the compliance standards in this partial final rule, only eight States would be out of compliance based on the fiscal year 2013 data, rather than the forty-eight States that would have been out of compliance under the standards in the proposed rule. In addition, in this partial final rule the revised definition of “detain or confine” clarifies, per the statute, that the term does not apply to situations where juveniles are being held solely pending their return to a parent or guardian or pending transfer to the custody of a child welfare or social services agency. Nor (in keeping with the statute) does it apply to situations where juveniles are held in a non-secure area of a building that also houses an adult jail or lockup. OJJDP expects that this clarification, along with the revised definition, will greatly reduce the amount of data that States will have to collect, compared to what they would have had to collect under the proposed definition. Finally, although the proposed rule would have required that 100% of facilities annually report compliance data, this partial final rule provides that States must submit

annual compliance data from only 85% of those facilities.

## II. Background

### A. Overview

This rule amends the regulation implementing the JJDP Formula Grant Program at 28 CFR part 31, authorized by 42 U.S.C. 5631(a). This section of the JJDP Act authorizes OJJDP to provide an annual grant to each State to improve its juvenile justice system and to support juvenile delinquency prevention programs.

### B. History of This Rulemaking

On August 8, 2016, OJP published a Notice of Proposed Rulemaking at 81 FR 52377, seeking comments on a rule that would have superseded the current Formula Grant Program regulation at 28 CFR part 31 in its entirety. The period for commenting on the proposed rule closed on October 7, 2016. During that period, OJJDP received 72 written comments, from a diverse array of respondents, representing State entities that administer the JJDP, child advocacy organizations, public interest groups, and individuals.

Based on the volume and complexity of the comments received, OJP has decided to publish a partial final rule to implement only some of the provisions included in the proposed rule as amendments to the current regulations. Many of the provisions included in the proposed rule, and responses to comments regarding those provisions, will be addressed in a future final rule, after further consideration.

### Changes Proposed in the Proposed Rule That Are Being Finalized in the Partial Final Rule<sup>2</sup>

1. The compliance standards included in section 31.9 of the proposed rule for the DSO, separation, and jail removal requirements have been significantly revised. This rule incorporates the revised language by amending section 31.303(f)(6) of the current regulation, through the adoption of a new methodology for determining the compliance standards on an annual basis.

2. The requirement in section 31.7(d)(1) of the proposed rule that States must annually submit compliance monitoring data from 100% of all facilities that are required to report such data has been modified. This rule amends section 31.303(f)(5) of the

<sup>2</sup> Because this partial final rule amends only certain sections of part 31, subpart A, rather than replacing the entire regulation (as the proposed rule would have done), the section numbers of these amended provisions correspond with the sections in the current regulations.

current regulations, such that States will be required to report data for 85% of facilities and demonstrate how they would extrapolate and report, in a statistically valid manner, data for the remaining 15% of facilities.

3. Consistent with the requirement in section 31.8(a) of the proposed rule, this rule amends section 31.303(f)(5) of the current regulations to change the compliance data reporting period to the federal fiscal year as required by the Act, at 42 U.S.C. 5633(c).

4. Instead of the proposed annual deadline of January 31st included in section 31.8(b) of the proposed rule for States to submit their compliance monitoring reports, this rule amends section 31.303(f)(5) of the current regulations to change the deadline to February 28th, with a provision allowing the Administrator to grant a one-month extension to March 31st upon a State’s showing of good cause.

5. This rule modifies the definition for “detain or confine” included in section 31.2 of the proposed rule. This rule adds this definition in subsection 31.304(q) of the current regulations, and clarifies that it does not apply to juveniles who are being held by law enforcement solely pending their reunification with a parent or guardian or pending transfer to the custody of a child welfare or social services agency.

### Changes Proposed in the Proposed Rule That Will Be Addressed in a Future Final Rule

1. Proposed changes to the Disproportionate Minority Contact (DMC) requirement;

2. Providing definitions for the following terms: “Administrator”, “alien”, “annual performance report”, “assessment”, “authorized representative”, “compliance monitoring report”, “construction fixtures”, “contact between juveniles and adult inmates”, “convicted”, “core requirements”, “designated state agency”, “DMC requirements”, “DSO requirements”, “extended juvenile court jurisdiction”, “full due process rights guaranteed to a status offender by the Constitution of the United States”, “jail removal requirements”, “juvenile”, “juveniles alleged to be or found to be delinquent”, “juveniles who are accused of nonstatus offenses”, “minority groups”, “monitoring universe”, “non-secure facility”, “placed or placement”, “public holidays”, “residential”, “responsible agency official”, “separation requirements”, “status offender”, “status offense”, “twenty-four hours”;



3. Proposed deletion of text in the current regulation that is repetitive of statutory provisions;

4. Proposed deletion of the Federal wards provision in the current regulation;

5. Proposed deletion of provisions in the current regulation rendered obsolete by the 2002 JJDP reauthorization;

6. Proposed deletion of requirements in the current regulation not specific to the formula grant program and are found elsewhere such as in the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, at 2 CFR part 200;

7. Proposed deletion of provisions that describe recommendations rather than requirements;

8. Proposed deletion of provisions that are unnecessary or duplicative of the formula grant program solicitation;

9. Prohibited discrimination provision (§ 31.4 in the proposed rule) (*i.e.*, the non-discrimination provision at 28 CFR 31.403—“Civil rights requirements”—remains in effect);

10. Proposed formula allocation (§ 31.5 in the proposed rule) (which would not alter the formula described in the Act at 42 U.S.C. 5632, but would simply require that a State’s annual allocation be based on data available from the U.S. Census Bureau);

The proposed provision (§ 31.8(c) in the NPRM) requiring that a designated State official certify that the information in the State’s compliance monitoring report is correct and complete is not being codified in this partial final rule, but this certification is already required under OJJDP’s current policy on “Monitoring of State Compliance with

the Juvenile Justice and Delinquency Prevention Act.”<sup>3</sup>

**III. Discussion of Comments and Changes Made by This Rule**

**A. Compliance Standards**

Based heavily on feedback from commenters, and in conjunction with statisticians in OJP’s Bureau of Justice Statistics, OJJDP has developed new compliance standards using the distribution of compliance rates reported in States’ compliance monitoring reports. The compliance standards included in section 31.303(f)(6) of this rule are significantly different from the standards contained in section 31.303(f)(6) of the current formula grant program regulations, as well as from those in the proposed rule. OJJDP believes that the methodology for establishing new compliance standards included in this partial final rule fully addresses the concerns raised by commenters, which are discussed more fully below.

**1. Revised Methodology for Determining Compliance Standards**

In determining the compliance standards, the distribution of each set of compliance rates (*i.e.*, for DSO, separation, and jail removal) using the average of two or more years of data (removing, when appropriate and applicable, one negative outlier each for DSO, separation, and jail removal) and applying a standard deviation factor of not less than one, will be analyzed to determine its mean, and standard deviations therefrom.

As provided in the final rule, section 31.303(f)(6) provides that, based on this information, a compliance rate that is not less than one standard deviation above the mean rate will be set as the compliance standard. Once established, the standards will be posted annually (in numerical form) on OJJDP’s Web site by August 31 of each year. Any State that reports a compliance rate above this compliance standard will be determined to be out of compliance. This methodology will not be applied, however, to States’ FY 2016 and FY 2017 compliance monitoring reports, in order to allow for a transition period.

**2. Standard for Determining Compliance Based on States’ FY 2016 Compliance Data**

Under the revised methodology described above, only data from Calendar Year (CY) 2013 will be used to establish standards for making compliance determinations based on States’ FY 2016 annual monitoring reports (affecting the FY 2017 awards). After removing one negative outlier from the DSO distribution (with a rate of 70.16 per 100,000 juvenile population), one negative outlier from the separation distribution (with a rate of 2.82 per 100,000 juvenile population), and one negative outlier in the jail removal distribution (with a rate of 82.8 per 100,000 juvenile population), the means without the negative outliers, the standard deviations, and what the compliance standards would be, based on two standard deviations above the means, is presented in the table below:

Core requirement	Current compliance standard	Mean without negative outlier	Standard deviation (SD)	Compliance standard (two SD from mean)
DSO .....	At or below 5.8, 5.9 to 17.6, 17.7 to 29.4	2.85	6.37	9.89
Separation .....	0 (with exceptions) .....	0.04	0.16	0.28
Jail Removal .....	At or below 9 .....	2.38	5.66	8.94

After removing the negative outlier from data for each of the three core requirements, the average rate, per 100,000 juvenile population, would be 2.85 for DSO, 0.04 for separation, and 2.38 for jail removal. Applying a standard deviation factor of 2 to each of these averages results in a final rate, per 100,000 juvenile population, of 9.89 for DSO, 0.28 for separation, and 8.94 for jail removal. States would need to be at, or below, these rates for OJJDP to find

them in compliance with the DSO, separation, and jail removal core requirements.

As provided in this rule, amending section 31.303(f)(6) of the current regulation, OJJDP will employ the methodology described above in establishing annual compliance standards for DSO, separation, and jail removal core requirements for determinations based on States’ FY 2016 data. Immediately following the

publication of this partial final rule, OJJDP will post the standards for determining compliance with the DSO, separation and jail removal requirements, which will be derived from CY 2013 data and will be used in making compliance determinations based on States’ FY 2016 compliance monitoring reports. These determinations will serve as the basis for establishing whether States will receive their full FY 2017 formula grant

<sup>3</sup>In any event, the report itself is subject to the False Statements Act, 18 U.S.C. 1001, as a matter of course.



allocation or their awards will be reduced for non-compliance.

3. Standard for Determining Compliance Based on States' FY 2017 Compliance Data

As provided in this rule, amending section 31.303(f)(6), in establishing compliance standards to apply to the FY 2017 compliance data (affecting the FY 2018 awards), OJJDP will take the

average of the combined CY 2013 and FY 2016 compliance data (removing, when appropriate/applicable, one negative outlier in each data collection period for DSO, separation, and jail removal) and apply a standard deviation factor of not less than one to establish the compliance standards to be applied to the FY 2017 compliance monitoring reports.

This methodology, which may result in compliance standards' being adjusted from one year to the next, recognizes the difficulty that States' face in preventing all instances of non-compliance with each core requirement and allows a State that reports a minimal number of such instances to be found in compliance and to continue to receive its full formula grant allocation.

Data used to establish compliance standards	Applied to compliance monitoring report year	Affecting fiscal year title II allocation
CY 2013 .....	FY 2016	FY 2017
CY 2013 and FY 2016 .....	FY 2017	FY 2018
FY 2016 and FY 2017 .....	FY 2018	FY 2019
FY 2017 and FY 2018 .....	FY 2019	FY 2020

4. Comments on Proposed Compliance Standards

OJJDP received numerous comments on the methodology for establishing the compliance standards in the proposed rule, and on the resulting standards published in the proposed rule. Commenters questioned the data used, the methodology employed to establish the standards, and the lack of opportunity to provide supporting documentation to address compliance deficiencies; they also raised the possibility of withdrawing from participation in the Formula Grant Program. Based on these comments, OJJDP has revised the compliance standards in the partial final rule, as discussed below, following a summary of the comments received.

A number of commenters raised concern with using data from only three States with the lowest rates of compliance, from each of the four Census Bureau regions. Several commenters also made the point that the data used in calculating the proposed compliance standards (CY 2013), did not include data based on the new guidance for "detain or confine," rendering the calculation unfair, arbitrary, rigid, and extreme. In addition, several States suggested that in calculating a rate for the compliance standards, OJP should use the average of two or three years of data from all States, and those data should include data based on the "detain or confine" guidance.

A number of commenters stated that it would be unfair not to allow States to provide additional documentation demonstrating how they would address violations as they occur, in order to demonstrate compliance. For example, under the current compliance standards

for DSO and jail removal, a State whose rate puts it out of compliance in principle could nevertheless demonstrate compliance with the *de minimis* standard by providing additional documentation (*i.e.*, recent passage of state law, or executive or judicial policy; or submission of an acceptable plan to eliminate the instances of non-compliance), that would allow it to be found in compliance.

Additionally, many commenters stated that if their State incurred just one DSO, separation, or jail removal violation, the State would be out of compliance under the proposed standards, resulting in a reduction of their formula grant allocation by 20% for each requirement with which the State is out of compliance. In addition, the State would be required to expend 50% of its remaining allocation to achieve compliance.

In response, although the current regulation permits States with a certain number of instances of non-compliance nevertheless to be found in compliance with the *de minimis* standards by providing additional documentation, OJJDP believes that the elimination of the subjective nature of this *de minimis* review will allow for a clearer and more objective process by which compliance determinations will be made.

OJJDP appreciates the thoughtful and detailed comments regarding the methodology used to establish the proposed compliance standards for the DSO, separation, and jail removal core requirements. OJJDP agrees that using data from all States, not just three States with the lowest violation rates, from each of the four Census Bureau regions, would provide for a more representative and balanced approach for establishing compliance standards.

5. States' Withdrawal From Participation in the Formula Grant Program

Several States questioned whether they would continue to participate in the Formula Grant Program, should the proposed compliance standards be implemented. It has never been OJJDP's intention to implement compliance standards that would discourage States' participation in the Formula Grant Program. OJJDP believes that the methodology described in this partial final rule to establish annual compliance standards is responsive to comments received and will encourage States' continued participation in the Formula Grant Program.

B. Revised Definition of "Detain or Confine"

The partial final rule contains a definition for the term "detain or confine" in section 31.304(q) that differs in some respects from what was in the proposed rule. In response to the many comments received, OJJDP has revised the definition in two key respects: To clarify that (1) a juvenile who was not actually free to leave was "detained," regardless of whether he believed he was free to leave; and (2) juveniles who are being held by law enforcement personnel for their own safety, and pending their reunification with a parent or guardian or pending transfer to the custody of a child welfare or social service agency, are not "detained or confined" within the meaning of the JJDPA.

OJJDP recognizes that the definition in the proposed rule may not have made sufficiently clear that the primary question in determining whether a juvenile was detained is whether he was, in fact, free to leave. If law

enforcement personnel would not have allowed the juvenile to leave, he was necessarily being detained, and there is no need to inquire as to whether he *believed* he was free to leave. For this reason, OJJDP has revised the definition to indicate that “detain or confine” means to hold, keep, or restrain a person *such that he is not free to leave*. If law enforcement personnel indicate that the juvenile was free to leave, it would be incumbent upon them to explain how/ why the juvenile would have understood that he was free to leave.

This revised definition also allows law enforcement to hold juveniles who (for example) are runaways, abandoned, endangered due to mental illness, homelessness, or drug addiction, or are victims of sex trafficking or other crimes, held pending their return to their parent or guardian or while law enforcement locates a safe environment in which to place them. In such instances, juveniles would not be considered to be “detained or confined” at all.

Before addressing the specific comments regarding the definition of “detain or confine” that was included in the proposed rule, OJJDP offers additional clarification of the impact of the definition of “detain or confine,” as used in the separation and jail removal requirements at 42 U.S.C. 5633(a)(12) and (13), respectively. First, those core requirements are applicable only in specific types of facilities. In determining whether there has been an instance of non-compliance with either of these core requirements, it is critical to note that the threshold inquiry must be “In what type of facility was the juvenile held?” An instance of non-compliance with the separation requirement can occur only in secure facilities in which juveniles have sight and sound contact with adult inmates.<sup>4</sup> An instance of non-compliance with the jail removal requirement can occur only in a jail or lockup for adults, as defined at 42 U.S.C. 5603(22). If the juvenile was not held in one of these types of facilities, the inquiry ends there, and

<sup>4</sup> Under 42 U.S.C. 5633(a)(12), the separation requirement is implicated when a juvenile is detained or confined in any institution in which he has contact with an adult inmate. “Contact” is defined at 42 U.S.C. 5603(25) as “the degree of interaction allowed between juvenile offenders in a *secure custody status* and incarcerated adults” under 28 CFR 31.303(d)(1)(i) (emphasis added). In turn, section 31.303(d)(1)(i) states: “A juvenile offender in a *secure custody status* is one who is physically detained or confined in a *locked room or other area set aside or used for the specific purpose of securely detaining persons who are in law enforcement custody*” (emphasis added). Read together, these provisions indicate that “institution” as used in the separation requirement must be understood to be a secure facility.

there can be no instance of non-compliance. Only if the facility is a jail or lockup for adults or is a secure facility or a secure area within a facility in which adult inmates are detained must it be determined whether the juvenile was detained or confined therein. For this reason, States need not monitor and report on “*Terry*” investigative stops on the street or instances in which juveniles are detained within a public or private school, or anywhere other than a jail or lockup for adults, or a secure facility in which adult inmates are detained or confined.

OJP received many questions regarding whether specific scenarios would constitute a juvenile’s being detained or confined, under the definition in the proposed rule. Because these were questions, rather than comments on the proposed rule, OJJDP will address them through guidance on OJJDP’s Web site. OJJDP also encourages States to submit any additional questions about specific fact patterns, which will be posted along with answers on OJJDP’s Web site.

#### Comment That OJP Is Incorrectly Using “Miranda” Standards in Defining “Detain or Confine”

Several commenters objected to OJJDP’s adherence to Fourth Amendment jurisprudence in determining an appropriate definition of the phrase “detain or confine.”

In response, despite these commenters’ opinions to the contrary, Fourth Amendment jurisprudence is applicable in the context of defining “detain or confine” for the purposes of the JJDP, as the plain language of that phrase references the restraining of an individual’s (in this context, a juvenile’s) liberty, which, as the U.S. Supreme Court noted in *U.S. v. Mendenhall*, 446 U.S. 544, 552 (1980), is the very definition of a “seizure.”<sup>5</sup> Thus, OJJDP does not agree with the argument that the application of Fourth Amendment jurisprudence generally, and/or the standards set forth in *Mendenhall* specifically, is improper.

Moreover, while OJJDP recognizes that *Mendenhall* was in fact a case involving an adult, the U.S. Supreme Court has never limited the Fourth Amendment protections enumerated

<sup>5</sup> As noted in the proposed rule, per *U.S. v. Mendenhall*, the Fourth Amendment governs all “seizures” of the person, “including seizures that involve only a brief detention short of traditional arrest.” See 446 U.S. 544, 547 (1980). Further, a “seizure” for the purposes of the Fourth Amendment has occurred when an officer “by means of physical force or a show of authority, has in some way restrained the liberty of a citizen.” *Id.* at 548.

therein to the adult population. Indeed, the U.S. Supreme Court has consistently recognized that, due to the inherent differences between adults and juveniles (in terms of maturity and reasoning), juveniles should, in certain circumstances, be afforded *more* protections than adults would be. One such example is the U.S. Supreme Court’s decision in *J.D.B. v. North Carolina*, 564 U.S. 261 (2011). Contrary to some commenters’ understanding, *J.D.B. v. North Carolina* did not establish a *de facto* “reasonable minor” standard for determining juvenile custody that was somehow separate from the standard established in *Mendenhall*. Rather, the Supreme Court’s decision in *J.D.B.*—that a juvenile’s age may affect his or her perception(s) of his or her interactions with law enforcement, and a juvenile’s age, therefore, must be one of many factors considered in any determination of whether the interrogation of the juvenile was a “custodial interrogation” for the purposes of *Miranda* warnings—was an explicit acknowledgement that Fourth Amendment protections espoused in *Mendenhall* not only extend to juveniles, but actually may be expanded under some circumstances where juveniles are concerned. Nonetheless, OJJDP has considered the commenters’ stated objections to the application of Fourth Amendment jurisprudence and has revised the definition to clarify that whether the juvenile is, in fact, free to leave is the critical factor in determining whether he is detained. If he is not, in fact, free to leave, as OJJDP expects will be the case in the vast majority of instances, he is detained.

#### Comments Received Regarding Proposed Definition of “Detain or Confine”

One commenter questioned the reason for the proposed definition, stating that there has been either no research or at least no broadly published research that a significantly widespread problem exists that supports the implementation of the new definition.

In response, OJJDP notes that the purpose of including the definition of “detain or confine” in the proposed rule, and in the partial final rule, is to clarify that the separation and jail removal requirements are implicated when a juvenile is detained in certain settings, regardless of whether he is “securely” detained. As noted above, the word “detain” has a plain meaning in 4th Amendment jurisprudence. Under that jurisprudence, one can be detained without being “securely” detained such as by a show of authority.

(*Terry v. Ohio*, 392 U.S. 1, 20, n.16 (1968)). Therefore, the absence of the word “securely” before “detain” in the JJDP Act indicates that, on its face, the statutory term is not limited to juveniles who are “securely” detained. Consistent with the definition of “detain or confine” in the proposed rule, and with the revised definition included in this partial final rule, the current regulation is being amended by removing the word “securely”. To understand “detained” to refer only to juveniles who are “securely” detained would be to read a word into the statute that is simply not there.

Several commenters contended that the proposed definition of “detain or confine” is contrary to the intent of the drafters of the JJDP Act, which was to protect juveniles held in secure custody. Because the term “detain or confine” is itself unambiguous, there is neither room for interpretation of the term nor warrant to attempt to determine—beyond what the plain text of the statute itself indicates—the “intent” of the drafters. Thus, OJJDP has not changed the definition to mean only secure detention.<sup>6</sup>

One commenter suggested that OJJDP is proposing a new definition of “detain or confine,” in order to address problems in select jurisdictions, and that research should be conducted to determine the extent of the problem of “youth languishing in law enforcement custody in a non-secure environment.” In response, OJJDP believes that the commenter misunderstood the purpose for the inclusion of this definition, which is not to address concerns within specific jurisdictions, but to conform more closely to the JJDP Act and to clarify for all jurisdictions the plain meaning of the term used in the statute.

#### Concern About Law Enforcement’s Ability To Detain Juveniles Temporarily, for Their Own Safety

Many commenters recommended that OJJDP maintain the current definition of “detain or confine,” which requires the physical restraint of a juvenile in a holding cell or locked interview room or by cuffing to a stationary object, because that would allow law enforcement to continue to detain a juvenile non-securely in a law enforcement facility for his own safety, and pending his

<sup>6</sup> A juvenile could be non-securely detained in a secure facility or secure area of an adult jail or lockup. For instance, the juvenile might physically be in the jail or lockup area, sitting in a chair without handcuffs or other restraints, but “detained” as the result of a show of authority by a law enforcement official present, making it clear the juvenile is not free to leave, which would result in an instance of non-compliance with the jail removal and possibly separation requirements.

return to his parent or guardian, without its resulting in an instance of non-compliance. Several commenters also stated that the proposed definition would give law enforcement the incentive to charge juveniles with a delinquent offense, or to charge them as adults because States could then detain them securely without a resulting instance of non-compliance.

In response, as explained above, OJJDP’s revised definition in this rule clarifies that when law enforcement personnel are holding a juvenile only pending his return to his parent or guardian or pending his transfer to the custody of a child welfare or social service agency, he is not detained. OJJDP believes that the revised definition will allay the concerns raised by many commenters that under the proposed definition of “detain or confine,” law enforcement would have a disincentive to bring status offenders or non-offenders (such as runaways) to a law enforcement facility to hold them until a parent or guardian could pick them up.

One commenter requested that OJJDP clearly specify who qualifies as a parent or guardian, but that is a determination that should be made according to the law of the relevant State.

Several commenters questioned whether liability would attach if law enforcement personnel were to tell a juvenile that he was free to leave a law enforcement facility, the juvenile did leave the law enforcement facility, and as a result the juvenile suffered some harm. OJP believes it would not be appropriate for OJP to provide legal advice to States as to whether law enforcement personnel or a law enforcement agency could be held liable in such a situation.

How will law enforcement know what a juvenile reasonably believes?

Many commenters stated that the proposed definition of “detain or confine” is vague, ambiguous, or confusing in that it is difficult to know whether a juvenile in a particular situation would have understood that he was free to leave. Several commenters also stated that the proposed definition is too subjective and will make it extremely difficult for law enforcement to know when a juvenile is being “detained” for purposes of the Formula Grant Program.

OJJDP disagrees that the definition is vague, ambiguous or confusing. As noted above, the key question is whether the juvenile was, in fact, free to leave the law enforcement facility, because the juvenile’s state of mind is irrelevant if he was not free to leave.

Under the revised definition in this partial final rule, it is only in instances where law enforcement personnel assert that the juvenile actually was free to leave that the inquiry next proceeds to whether the juvenile understood that he was free to leave. Contrary to the commenters’ assertions, however, this second inquiry does not necessitate that law enforcement “read the minds of juveniles” or determine whether a “reasonable juvenile” would have felt free to leave. Rather, in keeping with applicable Fourth Amendment jurisprudence, this second determination requires an objective examination of the circumstances surrounding the juvenile’s interaction with law enforcement, including any circumstance that would have affected how a reasonable person in the juvenile’s position would perceive his or her freedom to leave. Because a juvenile’s age may affect how a reasonable person in his position would perceive his freedom to leave, consistent with U.S. Supreme Court precedent, where the juvenile’s age is known to law enforcement, it must be a factor that is taken into consideration in making the determination. *See J.D.B.*, 564 U.S. at 275–77. It bears noting that the juvenile’s age may not be determinative, or even a significant factor, in every case; but it is one objective factor that must be taken into consideration, along with other objective factors such as the location(s) of the juvenile’s interaction(s) with law enforcement, the duration of law enforcement’s interaction(s) with the juvenile, the number of law enforcement officers present during the interaction(s), and any other circumstances surrounding the juvenile’s time in the presence of law enforcement that may inform a determination as to whether the juvenile understood he was free to leave.

One commenter stated that whether a juvenile believes he is free to leave is irrelevant to whether he is protected from potential harm by being in contact with an adult inmate. The same commenter stated that law enforcement personnel have the ability “simply by their presence . . . [to] limit conversation or other interaction between the juvenile and any adult inmate, thus limiting potential for harm.” In response, OJJDP believes that the commenter’s quarrel is with the JJDP Act itself. By its express terms, the statute’s separation requirement is implicated when a juvenile is detained or confined in any institution in which he has contact with an adult inmate, regardless of whether law enforcement

personnel are present and able to limit his interaction with an adult inmate.

How will law enforcement document whether a juvenile knew that he was free to leave?

At least one commenter noted that the proposed definition of “detain or confine” would cause a burden to law enforcement and complicate compliance monitoring activity, noting it will be cumbersome for law enforcement officers to collect relevant information every time a juvenile is brought to their departments. Additionally, several commenters questioned how law enforcement would document whether a juvenile knew that he was free to leave. In the preamble to the proposed rule, OJJDP gave as an example that law enforcement could produce a video recording of the juvenile indicating that he understood that he was free to leave. Commenters stated that requiring law enforcement personnel to make such a video recording is impractical and cost-prohibitive. OJJDP understands the additional burden that would create for a law enforcement agency. A more practical method of indicating that a juvenile understood that he was free to leave would be for law enforcement personnel to have the juvenile sign a form indicating that he understood he was free to leave, or for a law enforcement official to sign a form certifying that the juvenile was advised that he was free to leave.

One commenter expressed concern that juveniles who would not otherwise have their information put into a law enforcement database might now be entered into the system. We note that States could use paper forms that would be made available to the State’s compliance monitor but need not be entered into any law enforcement computer system.

#### Applicability of Term “Detain or Confine” to the DSO Requirement

Several commenters questioned the use of the term “detain or confine” within the context of the DSO requirement. The commenter is correct that, unlike the separation and jail removal requirements, in which the term “detain or confine” is used, the DSO requirement is implicated when a juvenile is “placed” in a secure detention or secure correctional facility. The commenter asserted that the use of a different term—“placed”—for the DSO requirement—thus indicates that the term means something other than simply “detained or confined.”

In response, OJJDP notes that the “placement” of a juvenile in a secure detention or secure correctional facility

means, at a minimum, that he is not free to leave and is, therefore detained (and confined). Therefore, a juvenile who has been “placed” has *necessarily* been “detained or confined.”

In the proposed rule, for the purposes of determining whether the DSO requirement would be applicable, OJJDP had included a proposed definition of the term “placed or placement” to clarify that it would refer, not to *mere* “detention or confinement,” but to circumstances where detention or confinement within a secure juvenile detention or correctional facility has resulted in a “placement.” Many commenters noted concerns about the proposed definition of “placed or placement.” The partial final rule does not include a definition of “placed or placement.” This issue will be addressed in a future final rule, and OJJDP will respond to all comments regarding this issue in detail in the subsequent final rule.

#### Whether a Juvenile’s Participation in a “Scared Straight” or “Shock Incarceration” Program Would Result in Non-Compliance With the Jail Removal and/or Separation Requirements

A commenter questioned whether, under the proposed rule, a juvenile under public authority could be required to participate in a “Scared Straight” or “shock incarceration” program in which he is brought into contact with an adult within an adult jail or lockup or in a secure correctional facility for adults, as a means of modifying his behavior. The commenter asked whether such participation would result in an instance of non-compliance with the jail removal and/or separation requirements when a parent has consented to the child’s participation in the program, or in an instance in which the juvenile who is participating in the program as a form of diversion fails to complete the program and the original charge is reinstated. The commenter is apparently questioning whether the voluntariness of a juvenile’s participation, and whether there would be consequences for not participating, in such a program would determine whether or not he was “detained” within sight or sight or sound contact of an adult inmate, resulting in an instance of non-compliance.

In response, OJJDP notes that whether such programs may result in instances of non-compliance with the separation and/or jail removal requirements will depend on the specific manner in which the program operates and the circumstances of the juveniles’ participation in the program. A key factor in determining whether instances

of non-compliance have occurred is whether juveniles participating in the program were free to leave the program while in sight or sound contact with adult inmates, regardless of whether the juvenile’s initial participation was voluntary. If a parent or guardian has consented to his child’s participation and may withdraw that consent at any time, the juvenile is not detained. States are encouraged to contact OJJDP for guidance about whether a particular program is resulting in—or has resulted in—instances of non-compliance. Generally speaking, if a juvenile participates in a program as a condition of diversion from the juvenile justice system, and does so with a parent’s or guardian’s consent, he is not detained, regardless of whether his failure to complete the program would result in the reinstatement of a charge against him.

#### Applicability of Proposed Definition of “Detain or Confine” to the Six-Hour Exception in the JJDP Act at 42 U.S.C. 5633(a)(13)(A)

Several commenters questioned how the proposed definition would apply to the provision allowing States to detain an accused delinquent offender for up to six hours for processing or release, while awaiting transfer to a juvenile facility, or in which period such juveniles make a court appearance, without a resulting instance of non-compliance. In response, OJJDP believes that no change in the final definition is needed in response to this comment. The definition in this rule would not alter the JJDP Act exception at 42 U.S.C. 5633(a)(13)(A) that allows States to detain an accused delinquent offender for up to 6 hours for those purposes.

#### Applicability of Proposed Definition of “Detain or Confine” to Juveniles Under Criminal Jurisdiction

One commenter stated that there should be an exception to the application of the proposed definition of “detain or confine” for juveniles waived or transferred to a criminal court. In response, OJJDP believes that no change in the final definition is needed in response to this comment. The core requirements do not apply to juveniles who are under criminal court jurisdiction.

#### Recommending a “Rural Exception” to the New Definition

Another commenter recommended that if OJJDP decides to alter the current definition of “detain or confine”, it should create a “rural exception” to the rule that would allow non-metropolitan areas to continue to use the current

definition. OJJDP has no authority under the JJDP Act to allow certain States or localities to use a different definition of the term “detain or confine.”

#### Proposed Alternative Definition of “Detain or Confine”

One commenter recommended that OJJDP remove the word “detain” from the definition and focus only on the confinement of juveniles, which the commenter asserts would be consistent with guidance provided in a memo from the OJJDP Administrator dated February 13, 2008. The Administrator’s memorandum discusses the definition of an adult lockup, relevant to determining the facilities in which an instance of non-compliance with the jail removal requirement can occur. In response, OJJDP believes that no change in the definition is needed in response to this comment. The instances of non-compliance with the jail removal requirement addressed in the Administrator’s memorandum can occur only in facilities that meet the definition of a “jail or lockup for adults” as defined in the JJDP Act at 42 U.S.C. 5603(22). That definition requires that the facility must be a “locked facility.” Thus, instances of non-compliance with the jail removal requirement cannot occur in non-secure facilities. Nor, as discussed above, would a juvenile’s detention in the non-secure portion of a law enforcement facility implicate the jail removal requirement.

#### Whether the Definition of “Detain or Confine” Will Expand the Monitoring Universe

Many commenters expressed concerns about whether the proposed rule would expand the types of facilities that must be included in the monitoring universe. In response, OJJDP has concluded that the definition of “detain or confine” in this final rule does not expand the current monitoring universe and that no change in the definition in the final rule is needed in response to this comment. Under OJJDP’s current guidance, the following facilities must be monitored: Adult jails and lockups, secure detention facilities, secure correctional facilities, court holding facilities, and collocated facilities (which includes facilities previously listed). Non-secure facilities must be monitored periodically to ensure that they have not changed characteristics such that they have become secure facilities. OJJDP will respond to all comments regarding the scope of the monitoring universe in greater detail in the subsequent final rule that will be published in the future with respect to

matters not covered in this partial final rule.

What data are expected for a compliance monitor to collect in order to monitor adequately?

Many commenters questioned what additional data would be required under the proposed definition of “detain or confine,” and how those data should be collected. Under the proposed rule, as well as under the revised definition in this rule, law enforcement personnel in adult jails and lockups and other secure facilities in which both juveniles and adult inmates are detained, would be required to keep logs regarding juveniles who are detained securely and non-securely (and not merely those *securely* detained, as States have done previously). It is important to note here that such logs should not include juveniles detained—either securely or non-securely—in a non-secure area of a law enforcement facility, as the separation and jail removal requirements are not applicable in that context. It should be stressed here that the revised definition of “detain or confine” in this final rule does not include juveniles who are held solely pending return to their parents or guardians or pending transfer to a social service or child welfare agency, thus eliminating the need for States to collect data on juveniles held for these reasons. Similarly, law enforcement personnel in institutions (secure facilities) in which (1) accused or adjudicated delinquent offenders, (2) status offenders, and (3) non-offenders who are aliens (or are alleged to be dependent, neglected, or abused) might have contact with adult inmates, would be required to keep logs on when such juveniles did, in fact, have contact with adult inmates.

#### Need for Training and Technical Assistance

Several commenters expressed concern that OJJDP has not provided any training on the implementation of the “detain or confine” guidance, stating that it is unrealistic to expect States to apply this new guidance until appropriate training and technical assistance has been provided. Other commenters stated that it would be cost-prohibitive for States to provide such training to law enforcement personnel. Another commenter suggested that OJJDP should highlight successful models both for determining in what common situations a juvenile would likely believe he is not free to leave as well as examples of best practices for States with rural and/or diffuse populations.

In response, OJJDP intends to provide additional guidance materials regarding implementation of the proposed definition of “detain or confine” and is also planning to provide States with training in 2017 on how to monitor for, and collect and report data on compliance in accordance with that definition.

#### C. Requirement That 100% of Facilities Must Report Compliance Data

Many commenters expressed concern about the proposed requirement that 100% of facilities in their States be required to report annual compliance data.<sup>7</sup> Commenters expressed concern that it would not be possible to achieve the 100% threshold, raising a number of challenges they would face in collecting data from 100% of the facilities in their States, including lack of legislative authority, time constraints, and an increase in associated costs.

In response, OJJDP believes that many of the commenters’ concerns may have arisen from the belief that the proposed rule would have expanded the monitoring universe to include additional facilities with respect to which States are not currently collecting data. As discussed above, under the proposed rule and, more importantly, under this partial final rule, the monitoring universe does not change, and States will continue to be required to monitor adult jails and lockups, secure detention facilities, secure correctional facilities, and any other institutions (secure facilities) in which juveniles might have contact with adult inmates. (States must also continue to monitor non-secure facilities to ensure that they have not changed physical characteristics such that they have become secure facilities.)

A few commenters suggested that the number of facilities that must report be reduced. (Various commenters respectively suggested 85%, 90%, or 95% as being a more practical requirement than the 100% level in the proposed rule.) In response, OJJDP acknowledges and understands the challenges described by the States in their comments, and this partial final rule has revised the proposal, so that States will be required to collect and report compliance data for 85% of facilities and to demonstrate how they would extrapolate and report, in a statistically valid manner, data for the remaining 15% of facilities.

Under the JJDP Act at 42 U.S.C. 5633(a)(14), the state plan that each

<sup>7</sup> This requirement was included in OJJDP’s Policy: Monitoring of State Compliance with the Juvenile Justice and Delinquency Prevention Act, provided to States in October 2015.

State must submit in order to be eligible for Formula Grant Program funding must “provide for an adequate system of monitoring jails, detention facilities, corrections facilities, and non-secure facilities to insure that the [DSO, separation, and jail removal requirements] are met, and for *annual reporting of the results of such monitoring* to the Administrator.” (Emphasis added.) The statutory provision does not specifically require reporting from 100% of facilities in a State’s annual monitoring report, thus giving OJJDP the administrative discretion to permit States to report for less than 100% of all facilities in the State, provided that its monitoring system be adequate. It is in the exercise of this same administrative discretion that OJJDP for decades used (and promulgated in its regulations for this program) various *de minimis* standards that allowed for less than full compliance by States under appropriate circumstances. Cf. *Washington Red Raspberry Comm’n v. United States*, 859 F. 2d 898, 902 (Fed. Cir. 1988) (“The *de minimis* concept is well-established in federal law. Federal courts and administrative agencies repeatedly have applied the *de minimis* principle in interpreting statutes, even when Congress failed explicitly to provide for the rule.”)

A few commenters indicated concern with the “good cause” standard in the proposed rule allowing for waiver of the proposed requirement for States to report data from 100% of facilities. In response, OJJDP notes that the reduction from 100% to 85% of the number of facilities required to report eliminates the need for a waiver exception to the reporting requirement, and that proposal is not included in this final rule.

#### *D. Issues Relating to Reporting Compliance Data for Core Requirements*

##### 1. Reporting of Compliance Data Based on Federal Fiscal Years and Deadline for Reporting Compliance Data

Many commenters objected to the language in the proposed rule requiring that States provide compliance data on a fiscal-year basis, because of the shortened period States will have for submitting compliance data from the time the reporting period ends on September 30th of each year and the proposed deadline of January 31st for submitting their data. A few commenters noted that the period in which States will be collecting and verifying their data includes several holidays during which staff often take leave and also occurs during a period in

which weather conditions make travel difficult within many States.

Additionally, commenters expressed concern that this shortened timeframe would present significant challenges to submission of accurate data (especially in light of the requirement to collect data from 100% of facilities) and would require additional resources to do so. A few commenters recommended extending the deadline, for instance, to March 15th or March 31st.

OJJDP has carefully considered these comments. The JJDPA itself requires reporting data on a fiscal-year basis, which was the reason for conforming the regulatory reporting period to the statutory requirement.

In response to the concerns raised and balancing them with OJJDP’s need for sufficient time to complete compliance determinations that will inform that year’s awards, OJJDP has extended the deadline in this partial final rule to February 28th, with the possibility of an extension to March 31st if a State were to demonstrate good cause.

##### 2. Requirement That States Report Twelve Months of Data for Each Reporting Period

One commenter questioned whether the proposed requirement that 100% of facilities report compliance data annually would affect the requirement in section 31.303(f)(5) of the current regulation that States may submit a minimum of six months’ of data for a reporting period. The proposed rule indicated that States’ compliance monitoring reports must contain data for “one full federal fiscal year.”

In response, OJJDP has clarified the applicability of this language. This partial final rule amends section 31.303(f)(5) to delete the language allowing States to report “not less than six months of data,” thus making it clear that States are required to provide compliance data for the full twelve-month reporting period. (And, as noted above, this partial final rule provides that States must submit data from 85% of facilities that are required to report compliance data.)

#### **IV. Regulatory Certifications**

##### *Regulatory Flexibility Act*

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Office of Juvenile Justice and Delinquency Prevention has reviewed this regulation and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. The Formula Grant Program provides funding to States pursuant to a statutory

provision, which is not affected by this regulation. Because States have complete discretion as to which local governments and other entities will receive formula grant funds through subgrants, as well as the amount of any subgrants, this rule will have no direct effect on any particular local governments or entities.

OJJDP received more than one comment disagreeing with OJJDP’s assessment that the proposed regulation will not have a significant economic impact on a substantial number of small entities. OJJDP’s basis for so certifying is that the rule regulates only States and territories, which are the recipients of funding under the Formula Grant Program. Commenters argued that the proposed rule, if made final as proposed, potentially would result in as many as 48 States being out of compliance with one or more of the core requirements. One commenter notes that because the States are required by statute to pass through 66 $\frac{2}{3}$  percent of the funding, the basis for certifying there is no significant impact on a substantial number of small governmental entities is not plausible and that cutting the funding to that number of States would certainly affect a substantial number of small entities.

OJJDP disagrees with these comments because, as noted above, only grants to States and territories are regulated by the rule. Nonetheless, in this partial final rule, OJJDP has revised significantly the compliance standards, and expects that under the revised standards only eight States are likely to be out of compliance with one or more of the core requirements under the Act, and to receive a reduction in funding as a result.

##### *Executive Orders 12866 and 13563—Regulatory Review*

This rule has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review” section 1(b), Principles of Regulation, and in accordance with Executive Order 13563 “Improving Regulation and Regulatory Review” section 1(b), General Principles of Regulation.

The Office of Justice Programs has determined that this rule is a “significant regulatory action” under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget. This partial final rule makes important improvements in the setting of annual compliance standards for the States, clarifies the definition of “detain or confine,” and makes other

improvements in the administration of the Formula Grant Program. The total formula grant appropriation funding available to States for the last five years has been less than \$43 million per year.

Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits and costs are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitative values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

This most significant provision of this rule updates the standards for determining compliance with the DSO, separation, and jail removal requirements, which have not been updated since 1981 for DSO, 1994 for separation, and 1988 for jail removal. The new compliance standards in this rule were carefully considered in light of the potential costs and benefits that would result and are narrowly tailored to recognize the significant progress that States have made over the last 35 years while ensuring that States continue to strive to protect juveniles within the juvenile justice system.

#### *Executive Order 13132—Federalism*

One commenter stated that in the Regulatory Certifications section of the preamble to the proposed rule (section V.), “the classical argument between state rights vers[u]s federal powers is mentioned in great detail and so we feel should be addressed.” OJJDP does not agree that that section includes any discussion of States’ rights in relation to the federal government, or that any such discussion would be relevant. The Formula Grant Program does not impose any mandates on States; nor does it interfere with States’ sovereignty, authorities, or rights. States, rather, participate in the program voluntarily and, as a condition of receipt of funding to improve their juvenile justice systems and to operate juvenile delinquency prevention programs, agree to comply with the program’s requirements.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various

levels of government, as the rule only affects the eligibility for, and use of, federal funding under this program. The rule will not impose substantial direct compliance costs on State and local governments, or preempt any State laws. Therefore, in accordance with Executive Order No. 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### *Executive Order 12988—Civil Justice Reform*

This rule meets the applicable standards set forth in sections 3(a) & (b)(2) of Executive Order No. 12988. Pursuant to section 3(b)(1)(I) of the Executive Order, nothing in this or any previous rule (or in any administrative policy, directive, ruling, notice, guideline, guidance, or writing) directly relating to the Program that is the subject of this rule is intended to create any legal or procedural rights enforceable against the United States, except as the same may be contained within subpart B of part 94 of title 28 of the Code of Federal Regulations.

#### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. The Formula Grant Program provides funds to States to improve their juvenile justice systems and to support juvenile delinquency prevention programs. As a condition of funding, States agree to comply with the Formula Grant Program requirements. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Congressional Review Act*

This rule is not a major rule as defined by 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### *Paperwork Reduction Act*

This rule does not propose any new, or changes to existing, “collection[s] of information” as defined by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) and its

implementing regulations at 5 CFR part 1320.

#### **List of Subjects in 28 CFR Part 31**

Administrative practice and procedure, Formula Grant Program, Juvenile delinquency prevention, Juvenile justice, Juvenile Justice and Delinquency Prevention Act (JJDP).

Accordingly, for the reasons set forth in the preamble, part 31 of chapter I of Title 28 of the Code of Federal Regulations is amended as follows:

#### **PART 31—OJJDP GRANT PROGRAMS**

■ 1. The authority citation for 28 CFR part 31 is revised to read as follows:

**Authority:** 42 U.S.C 5611(b); 42 U.S.C. 5631–5633.

#### **Subpart A—Formula Grants**

##### **§ 31.303 Substantive requirements.**

■ 2. Amend § 31.303 as follows:

■ a. In paragraphs (e)(2), (e)(3)(i), and (f)(4)(vi), remove the words “secure custody” and add in their place “detention”.

■ b. Revise paragraph (f)(5) introductory text.

■ c. In paragraph (f)(5)(i)(D), remove the words “securely detained” and add in their place “detained”.

■ d. In paragraphs (f)(5)(iii)(C) and (f)(5)(iii)(D), remove the words “secure detention and confinement” and add in their place “detention and confinement”.

■ e. In paragraphs (f)(5)(iv)(F), (G), (H), and (I), remove the words “held securely” and add in their place “detained”.

■ f. Revise paragraph (f)(6).

The revisions read as follows:

##### **§ 31.303 Substantive requirements.**

\* \* \* \* \*

(f) \* \* \*

(5) *Reporting requirement.* The State shall report annually to the Administrator of OJJDP on the results of monitoring for the core requirements in the JJDP at 42 U.S.C. 5633(a)(12), (13), and (14). The reporting period should provide 12 months of data for each federal fiscal year, for 85% of facilities within the State that are required to report compliance data, and States must extrapolate and report, in a statistically valid manner, data for the remaining 15% of facilities. The report shall be submitted to the Administrator of OJJDP by February 28 of each year, except that the Administrator may grant an extension of the reporting deadline to March 31st, for good cause, upon request by a State.

\* \* \* \* \*



(6) *Compliance*. The State must demonstrate the extent to which the requirements of sections 223(a)(11), (12), and (13) of the Act are met.

(i) In determining the compliance standards to be applied to States' FY 2016 compliance monitoring data, the Administrator shall collect all of the data from each of the States' CY 2013 compliance reports, remove one negative outlier in each data collection period for DSO, separation, and jail removal, and apply a standard deviation factor of two to establish the compliance standards to be applied, which shall be posted on OJJDP's Web site no later than March 3, 2017.

(ii) In determining the compliance standards to be applied to States' FY 2017 compliance monitoring data, the Administrator shall collect all of the data from each of the States' CY 2013 and FY 2016 compliance reports (removing, when appropriate or applicable, one negative outlier in each data collection period for DSO, separation, and jail removal) and apply a standard deviation factor of not less than one to establish the compliance standards to be applied, which shall be posted on OJJDP's Web site by August 31, 2017.

(iii) In determining the compliance standards to be applied to States' FY 2018 and subsequent years' compliance monitoring data, the Administrator shall take the average of the States' compliance monitoring data from not less than two years prior to the compliance reporting period with respect to which the compliance determination will be made (removing, when applicable, one negative outlier in each data collection period for DSO, separation, and jail removal) and apply a standard deviation of not less than one to establish the compliance standards to be applied, except that the Administrator may make adjustments to the methodology described in this paragraph as he deems necessary and shall post the compliance standards on OJJDP's Web site by August 31st of each year.

\* \* \* \* \*

■ 3. Amend § 31.304 by adding paragraph (q) to read as follows:

**§ 31.304 Definitions.**

\* \* \* \* \*

(q) *Detain or confine* means to hold, keep, or restrain a person such that he is not free to leave, or such that a reasonable person would believe that he is not free to leave, except that a juvenile held by law enforcement solely for the purpose of returning him to his parent or guardian or pending his

transfer to the custody of a child welfare or social service agency is not detained or confined within the meaning of this definition.

Dated: January 10, 2017.

**Karol V. Mason,**

*Assistant Attorney General, Office of Justice Programs.*

[FR Doc. 2017-00740 Filed 1-13-17; 8:45 am]

**BILLING CODE 4410-18-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### 31 CFR Part 538

#### Sudanese Sanctions Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending the Sudanese Sanctions Regulations to authorize all prohibited transactions, including transactions involving property in which the Government of Sudan has an interest. OFAC is issuing this general license in connection with ongoing U.S.-Sudan bilateral engagement and in response to positive developments in the country over the past six months related to bilateral cooperation, the ending of internal hostilities, regional cooperation, and improvements to humanitarian access.

**DATES:** *Effective:* January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202-622-2480, Assistant Director for Regulatory Affairs, tel.: 202-622-4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202-622-2410.

**SUPPLEMENTARY INFORMATION:**

**Electronic Availability**

This document and additional information concerning OFAC are available from OFAC's Web site ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)).

**Background**

OFAC is amending the Sudanese Sanctions Regulations (the "Regulations") to add section 538.540, authorizing all transactions prohibited by the Regulations and by Executive Orders 13067 and 13412, effective as of

January 17, 2017. Newly authorized transactions include the processing of transactions involving persons in Sudan; the importation of goods and services from Sudan; the exportation of goods, technology, and services to Sudan; and transactions involving property in which the Government of Sudan has an interest.

OFAC is issuing this rule in connection with ongoing U.S.-Sudan bilateral engagement and in order to support and sustain positive developments in the country over the past six months. In conjunction with this engagement, the U.S. government has supported the Sudanese government's ongoing efforts, including its cessation of military offensives in Darfur and the Two Areas, its cooperative efforts to resolve the ongoing conflict in South Sudan and cease any activity to undermine stability there, to improve access for humanitarian assistance by reducing government obstruction and streamlining governing regulations, and to enhance bilateral counterterrorism and security cooperation, including efforts to counter the Lord's Resistance Army.

Notwithstanding these positive developments in Sudan and the decision to amend the Regulations today to authorize all transactions prohibited by the Regulations, section 906 of the Trade Sanctions Reform and Export Enhancement Act of 2000, as amended (22 U.S.C. 7201 *et seq.*) (TSRA), continues to require in pertinent part that the export of agricultural commodities, medicine, and medical devices to Sudan shall be made pursuant to one-year licenses issued by the U.S. government, except that the requirements of such one-year licenses shall be no more restrictive than general licenses administered by the Department of the Treasury. *See* 22 U.S.C. 7205(a)(1). Section 906 of TSRA also specifies that procedures be in place to deny licenses for certain exports of agricultural commodities, medicine, and medical devices to Sudan. As with a general license added to the Regulations in 2011 that authorized the exportation or reexportation of food to Sudan (*see* 31 CFR 538.523; 76 FR 63191 (October 12, 2011)), the new general license added today includes the one-year license requirement and, along with counterterrorism sanctions implemented by OFAC set forth in 31 CFR chapter V and other continuing requirements and authorities, satisfies TSRA's requirement that procedures be in place to deny authorization for exports to Sudan that are determined to be



promoting international terrorism. In particular, § 501.601 of the Reporting, Procedures and Penalties Regulations, 31 CFR part 501 (RPPR), requires that all U.S. persons maintain records of authorized transactions for a period of not less than five years and further provides that OFAC may obtain these records at any time to monitor activities conducted pursuant to the general license; section 538.502 of the Regulations provides that OFAC may exclude any person, property, or transaction from the operation of this general license; and section 501.803 of the RPPR provides that OFAC may amend, modify, or revoke this general license at any time.

This new general license does not eliminate the need to comply with other provisions of 31 CFR chapter V including those parts related to terrorism, the proliferation of weapons of mass destruction, or narcotics trafficking, or other applicable provisions of law, including any requirements of agencies other than OFAC. Such requirements include, for example, the Export Administration Regulations (15 CFR parts 730 through 774) administered by the Bureau of Industry and Security of the Department of Commerce. This general license does not affect past, present, or future enforcement actions or investigations with respect to any violations, including apparent or alleged violations, of the Regulations that occurred prior to the effective date of this final rule.

#### Public Participation

Because the amendment of the Regulations involves a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

#### Paperwork Reduction Act

The collections of information related to the Regulations are contained in the RPPR. Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

#### List of Subjects in 31 CFR Part 538

Administrative practice and procedure, Banks, Banking, Foreign trade, Sanctions, Services, Sudan.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR part 538 to read as follows:

#### PART 538—SUDANESE SANCTIONS REGULATIONS

■ 1. The authority citation for part 538 continues to read as follows:

**Authority:** 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); 22 U.S.C. 7201–7211; Pub. L. 109–344, 120 Stat. 1869; Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13067, 62 FR 59989, 3 CFR, 1997 Comp., p. 230; E.O. 13412, 71 FR 61369, 3 CFR, 2006 Comp., p. 244.

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

■ 2. Add § 538.540 to subpart E to read as follows:

##### § 538.540 All transactions authorized; Government of Sudan property unblocked.

(a) All transactions prohibited by this part and Executive Orders 13067 and 13412, including all transactions that involve property in which the Government of Sudan has an interest, are authorized.

(b) Pursuant to section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7205), any exports or reexports of agricultural commodities, medicine, or medical devices to the Government of Sudan, to any individual or entity in Sudan, or to any person in a third country purchasing specifically for resale to any of the foregoing must be shipped within the 12-month period beginning on the date of the signing of the contract for export or reexport.

**Note 1 to § 538.540:** Section 538.540 authorizes all transactions necessary to unblock any property or interests in property that were blocked pursuant to 31 CFR 538.201 prior to January 17, 2017, including the return or processing of funds.

**Note 2 to § 538.540:** This authorization is effective on January 17, 2017 and does not eliminate the need to comply with other provisions of 31 CFR chapter V or other applicable provisions of law, including any requirements of agencies other than the Department of the Treasury's Office of Foreign Assets Control. Such requirements include the Export Administration Regulations (15 CFR parts 730 through 774) administered by the Bureau of Industry and Security of the Department of Commerce and

the International Traffic in Arms Regulations (22 CFR parts 120 through 130) administered by the Department of State.

**Note 3 to § 538.540:** Consistent with section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7205), each year OFAC will determine whether to revoke this general license. Unless revoked, the general license will remain in effect.

Dated: January 10, 2017.

**John E. Smith,**

*Acting Director, Office of Foreign Assets Control.*

[FR Doc. 2017–00844 Filed 1–13–17; 8:45 am]

**BILLING CODE 4810–AL–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2017–0007]

RIN 1625–AA87

#### Security Zones; Annual Events in the Captain of the Port Detroit Zone—North American International Auto Show, Detroit River, Detroit MI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a security zone associated with the North American International Auto Show, Detroit River, Detroit, MI. This security zone is intended to restrict vessels from a portion of the Detroit River in order to ensure the safety and security of participants, visitors, and public officials at the North American International Auto Show (NAIAS), which is being held at Cobo Hall in downtown Detroit, MI. Vessels in close proximity to the security zone will be subject to increased monitoring and boarding during the enforcement of the security zone. No person or vessel may enter the security zone while it is being enforced without permission of the Captain of the Port Detroit.

**DATES:** The security zone regulation described in 33 CFR 165.915(a)(3) will be enforced from 8 a.m. on January 9, 2017 through 11:59 p.m. on January 22, 2017.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this document, call or email Tracy Girard, Prevention, U.S. Coast Guard Sector Detroit, 110 Mount Elliot Ave., Detroit, MI 48207; telephone (313) 568–9564; email [Tracy.M.Girard@uscg.mil](mailto:Tracy.M.Girard@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the North American International Auto Show, Detroit River, Detroit, MI security zone listed in 33 CFR 165.915(a)(3). This security zone includes all waters of the Detroit River encompassed by a line beginning at a point of origin on land adjacent to the west end of Joe Lewis Arena at 42°19.44' N., 083°03.11' W.; then extending offshore approximately 150 yards to 42°19.39' N., 083°03.07' W.; then proceeding upriver approximately 2000 yards to a point at 42°19.72' N., 083°01.88' W.; then proceeding onshore to a point on land adjacent the Tercentennial State Park at 42°19.79' N., 083°01.90' W.; then proceeding downriver along the shoreline to connect back to the point of origin. All coordinates are North American Datum 1983.

All persons and vessels shall comply with the instructions of the Captain of the Port Detroit or his designated on-scene representative, who may be contacted via VHF Channel 16.

Under the provisions of 33 CFR 165.33, no person or vessel may enter or remain in this security zone without the permission of the Captain of the Port Detroit. Each person and vessel in this security zone shall obey any direction or order of the Captain of the Port Detroit. The Captain of the Port Detroit may take possession and control of any vessel in this security zone. The Captain of the Port Detroit may remove any person, vessel, article, or thing from this security zone. No person may board, or take or place any article or thing on board any vessel in this security zone without the permission of the Captain of Port Detroit. No person may take or place any article or thing upon any waterfront facility in this security zone without the permission of the Captain of the Port Detroit.

Vessels that wish to transit through this security zone shall request permission from the Captain of the Port Detroit or his designated representative. Requests must be made in advance and approved by the Captain of Port before transits will be authorized. Approvals may be granted on a case by case basis. The Captain of the Port may be contacted via U.S. Coast Guard Sector Detroit on channel 16, VHF-FM. The Coast Guard will give notice to the public via Local Notice to Mariners and VHF radio broadcasts that the regulation is in effect.

This document is issued under authority of 33 CFR 165.915 and 5 U.S.C. 552 (a). If the Captain of the Port determines that this security zone need not be enforced for the full duration

stated in this document; he may suspend such enforcement and notify the public of the suspension via a Broadcast Notice to Mariners.

Dated: January 6, 2017.

**Scott B. Lemasters,**

*Captain, U.S. Coast Guard, Captain of the Port Detroit.*

[FR Doc. 2017-00464 Filed 1-12-17; 4:15 pm]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 17

**RIN 2900-AP57**

#### Repayment by VA of Educational Loans for Certain Psychiatrists; Correction

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule; correcting amendment.

**SUMMARY:** The Department of Veterans Affairs published in the **Federal Register** on September 29, 2016, a document amending its regulations concerning the repayment of educational loans for certain psychiatrists who agree to a period of obligated service with VA. The document contained several section and paragraph numbering errors. This document corrects the errors and does not make any substantive change to the content of the final rule.

**DATES:** *Effective Date:* January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Crystal Cruz, Deputy Director, Healthcare Talent Management (10A2A4), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420; (405) 552-4346. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** VA published a final rule in the **Federal Register** on September 29, 2016, which established into regulation Public Law 114-2, the Clay Hunt Suicide Prevention for American Veterans Act (Clay Hunt SAV Act), enacted on February 12, 2015. Section 4 of this Act establishes a pilot program for the repayment of educational loans for certain psychiatrists seeking employment in VA, which will be referred to as the Program for the Repayment of Educational Loans. The document contained several section and paragraph numbering errors, which will be corrected in this document. The **DATES** section of the final rule incorrectly cited § 17.644 as the section that contains the collection of

information. We are amending the **DATES** section to correctly state § 17.643 as the section that contains the collection of information. No other edits are made to the **DATES** section. Section 17.643 had two paragraphs that were numbered (c)(2)(ii). We are now redesignating the second paragraph (c)(2)(ii) in § 17.643 as paragraph (c)(2)(iii). No other edits are made to § 17.643. Section 17.644 did not have a paragraph (a)(3) and was, therefore, marked as reserved. We are now redesignating paragraphs (a)(4), (5), (6), (7), and (8) of § 17.644 as paragraphs (a)(3), (4), (5), (6), and (7). No other edits are made to § 17.644.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

#### Correction

In the final rule document published on September 29, 2016, at 81 FR 66815, make the following correction:

1. On page 66815, in the first column, in the **DATES** section, remove “§ 17.644” and add in its place “§ 17.643” to read as follows:

**DATES:** *Effective Date:* This rule is effective on September 29, 2016, except for § 17.643 which contains information collection requirements that have not been approved by OMB. VA will publish a document in the **Federal Register** announcing the effective date.

For the reasons set out in the preamble, VA is correcting 38 CFR part 17 by making the following correcting amendments:

#### PART 17—MEDICAL

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

**Authority:** 38 U.S.C. 501, and as noted in specific sections. Sections 17.640 and 17.647 also issued under Pub. L. 114-2, sec. 4.

Sections 17.641 through 17.646 also issued under 38 U.S.C. 501(a) and Pub. L. 114-2, sec. 4.

#### § 17.643 [Amended]

■ 2. In § 17.643, redesignate the second paragraph (c)(2)(ii) as paragraph (c)(2)(iii).

**§ 17.644 [Amended]**

■ 3. In § 17.644, redesignate paragraphs (a)(4), (5), (6), (7), and (8) as paragraphs (a)(3), (4), (5), (6), and (7).

Dated: January 5, 2017.

**Janet Coleman,**

*Chief, Regulation Policy & Management,  
Office of the Secretary, Department of  
Veterans Affairs.*

[FR Doc. 2017-00232 Filed 1-13-17; 8:45 am]

BILLING CODE 8320-01-P

**SURFACE TRANSPORTATION BOARD****49 CFR Part 1022**

[Docket No. EP 716 (Sub-No. 2)]

**Civil Monetary Penalties—2017 Adjustment**

**AGENCY:** Surface Transportation Board.

**ACTION:** Final rule.

**SUMMARY:** The Surface Transportation Board (Board) is issuing a final rule to implement the annual inflationary adjustment to its civil monetary penalties, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

**DATES:** This final rule is effective January 17, 2017, and is applicable beginning January 13, 2017.

**FOR FURTHER INFORMATION CONTACT:** Sarah Fancher: (202) 245-0355. Federal Information Relay Service (FIRS) for the hearing impaired: 1-800-877-8339.

**SUPPLEMENTARY INFORMATION:****I. Background**

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), passed as part of the Bipartisan Budget Act of 2015, Public Law 114-74, 129 Stat. 599, requires agencies to adjust their civil penalties for inflation annually, beginning on January 15, 2017, and no later than January 15 of every year thereafter. In accordance with the 2015 Act, annual inflation adjustments will be based on the percent change between the Consumer Price Index for all Urban Consumers (CPI-U) for October of the previous year and the October CPI-U of the year before that. Penalty level adjustments should be rounded to the nearest dollar.

**II. Discussion**

The statutory definition of civil monetary penalty covers various civil penalty provisions under the Rail (Part A), Motor Carriers, Water Carriers, Brokers, and Freight Forwarders (Part B), and Pipeline Carriers (Part C) provisions of the Interstate Commerce

Act, as amended by the ICC Termination Act of 1995. The Board's civil (and criminal) penalty authority related to rail transportation appears at 49 U.S.C. 11901-11908. The Board's penalty authority related to motor carriers, water carriers, brokers, and freight forwarders appears at 49 U.S.C. 14901-14915. The Board's penalty authority related to pipeline carriers appears at 49 U.S.C. 16101-16106.<sup>1</sup> The Board has regulations at 49 CFR pt. 1022, which codify the method set forth in the 2015 Act for annually adjusting for inflation the civil monetary penalties within the Board's jurisdiction.<sup>2</sup>

As set forth in this final rule, the Board is amending 49 CFR pt. 1022 so that its regulations and civil monetary penalties conform to the requirements of the 2015 Act. The adjusted penalties set forth in the rule will apply only to violations which occur after the effective date of this regulation.

In accordance with the 2015 Act, the annual adjustment adopted here is calculated by multiplying each current penalty by the cost-of-living adjustment factor of 1.01636, which reflects the percentage change between the October 2016 CPI-U (724.113) and the October 2015 CPI-U (712.458). The table at the end of this decision shows the relevant statutory provision of each civil penalty and a description, the current baseline statutory civil penalty level, and the adjusted statutory civil penalty level for 2017.

**III. Final Rule**

The final rule is set forth at the end of this decision. This final rule is issued without prior public notice or opportunity for public comment. The Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), does not require that process "when the agency for good cause finds" that public notice and comment are "unnecessary." Here, Congress has mandated that the agency make the inflation adjustment to its civil monetary penalties. The Board has no discretion to set alternative levels of adjusted civil monetary penalties, because the amount of the inflation adjustment must be calculated in accordance with the statutory formula. The Board simply determines the

<sup>1</sup> The Board also has criminal penalty authority, enforceable in a federal criminal court. Congress has not, however, authorized federal agencies to adjust statutorily-prescribed criminal penalty provisions for inflation, and this rule does not address those provisions.

<sup>2</sup> The current statutory civil penalties were set through an interim final rule, *Civil Monetary Penalty Inflation Adjustment Rule*, EP 716 (Sub-No. 1) (STB served Oct. 20, 2016). In that decision, the Board issued a "catch-up adjustment" for its civil monetary penalties as mandated by the 2015 Act.

amount of inflation adjustments by performing technical, ministerial computations. Because the Board has no discretion to do anything except promulgate the rule and perform ministerial computations to apply it, the Board has determined that there is good cause to promulgate this rule without soliciting public comment and to make this regulation effective immediately upon publication.

**IV. Regulatory Flexibility Statement**

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because the Board has determined that notice and comment are not required under the APA for this rulemaking, the requirements of the RFA do not apply.

**V. Paperwork Reduction Act**

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

**List of Subjects in 49 CFR Part 1022**

Administrative practice and procedures, Brokers, Civil penalties, Freight forwarders, Motor carriers, Pipeline carriers, Rail carriers, Water carriers.

*It is ordered:*

1. The Board amends its rules as set forth in this decision. Notice of the final rule will be published in the **Federal Register**.

2. This decision is effective on its date of service.

Decided: January 9, 2017.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

**Kenyatta Clay,**

*Clearance Clerk.*

For the reasons set forth in the preamble, part 1022 of title 49, chapter X, of the Code of Federal Regulations is amended as follows:

**PART 1022—CIVIL MONETARY PENALTY INFLATION ADJUSTMENT**

■ 1. The authority citation for part 1022 continues to read as follows:

**Authority:** 5 U.S.C. 551-557; 28 U.S.C. 2461 note; 49 U.S.C. 11901, 14901, 14903, 14904, 14905, 14906, 14907, 14908, 14910, 14915, 16101, 16103.

■ 2. Revise § 1022.4(b) to read as follows:

**§ 1022.4 Cost-of-living adjustments of civil monetary penalties.**

\* \* \* \* \*

(b) The cost-of-living adjustment required by the statute results in the

following adjustments to the civil monetary penalties within the jurisdiction of the Board:

U.S. code citation	Civil monetary penalty description	Baseline penalty amount	Adjusted penalty amount (2017)
<b>Rail Carrier Civil Penalties</b>			
49 U.S.C. 11901(a)	Unless otherwise specified, maximum penalty for each knowing violation under this part, and for each day.	\$7,512	\$7,635
49 U.S.C. 11901(b)	For each violation under § 11124(a)(2) or (b)	751	763
49 U.S.C. 11901(b)	For each day violation continues	38	39
49 U.S.C. 11901(c)	Maximum penalty for each knowing violation under §§ 10901–10906	7,512	7,635
49 U.S.C. 11901(d)	For each violation under §§ 11123 or 11124(a)(1)	150–751	152–763
49 U.S.C. 11901(d)	For each day violation continues	75	76
49 U.S.C. 11901(e)(1)	For each violation under §§ 11141–11145	751	763
49 U.S.C. 11901(e)(2)	For each violation under § 11144(b)(1)	150	152
49 U.S.C. 11901(e)(3–4)	For each violation of reporting requirements, for each day	150	152
<b>Motor and Water Carrier Civil Penalties</b>			
49 U.S.C. 14901(a)	Minimum penalty for each violation and for each day	1,028	1,045
49 U.S.C. 14901(a)	For each violation under §§ 13901 or 13902(c)	10,282	10,450
49 U.S.C. 14901(a)	For each violation related to transportation of passengers	25,705	26,126
49 U.S.C. 14901(b)	For each violation of the hazardous waste rules under § 3001 of the Solid Waste Disposal Act.	20,564–41,128	20,900–41,801
49 U.S.C. 14901(d)(1)	Minimum penalty for each violation of household good regulations, and for each day.	1,502	1,527
49 U.S.C. 14901(d)(2)	Minimum penalty for each instance of transportation of household goods if broker provides estimate without carrier agreement.	15,025	15,271
49 U.S.C. 14901(d)(3)	Minimum penalty for each instance of transportation of household goods without being registered.	37,561	38,175
49 U.S.C. 14901(e)	Minimum penalty for each violation of a transportation rule	3,005	3,054
49 U.S.C. 14901(e)	Minimum penalty for each additional violation	7,512	7,635
49 U.S.C. 14903(a)	Maximum penalty for undercharge or overcharge of tariff rate, for each violation.	150,245	152,703
49 U.S.C. 14904(a)	For first violation, rebates at less than the rate in effect	300	305
49 U.S.C. 14904(a)	For all subsequent violations	376	382
49 U.S.C. 14904(b)(1)	Maximum penalty for first violation for undercharges by freight forwarders.	751	763
49 U.S.C. 14904(b)(1)	Maximum penalty for subsequent violations	3,005	3,054
49 U.S.C. 14904(b)(2)	Maximum penalty for other first violations under § 13702	751	763
49 U.S.C. 14904(b)(2)	Maximum penalty for subsequent violations	3,005	3,054
49 U.S.C. 14905(a)	Maximum penalty for each knowing violation of § 14103(a), and knowingly authorizing, consenting to, or permitting a violation of § 14103(a) & (b).	15,025	15,271
49 U.S.C. 14906	Minimum penalty for first attempt to evade regulation	2,056	2,090
49 U.S.C. 14906	Minimum amount for each subsequent attempt to evade regulation	5,141	5,225
49 U.S.C. 14907	Maximum penalty for recordkeeping/reporting violations	7,512	7,635
49 U.S.C. 14908(a)(2)	Maximum penalty for violation of § 14908(a)(1)	3,005	3,054
49 U.S.C. 14910	When another civil penalty is not specified under this part, for each violation, for each day.	751	763
49 U.S.C. 14915(a)(1) & (2)	Minimum penalty for holding a household goods shipment hostage, for each day.	11,940	12,135
<b>Pipeline Carrier Civil Penalties</b>			
49 U.S.C. 16101(a)	Maximum penalty for violation of this part, for each day	7,512	7,635
49 U.S.C. 16101(b)(1) & (4)	For each recordkeeping violation under § 15722, each day	751	763
49 U.S.C. 16101(b)(2) & (4)	For each inspection violation liable under § 15722, each day	150	152
49 U.S.C. 16101(b)(3) & (4)	For each reporting violation under § 15723, each day	150	152
49 U.S.C. 16103(a)	Maximum penalty for improper disclosure of information	1,502	1,527

# Proposed Rules

Federal Register

Vol. 82, No. 10

Tuesday, January 17, 2017

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

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 319

[Docket No. APHIS–2016–0022]

RIN 0579–AE29

#### Importation of Hass Avocados From Colombia

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** We are reopening the comment period for a proposed rule to allow the importation of Hass avocados from Colombia into the continental United States. We are also notifying the public of the availability of a revised pest risk assessment and risk management document associated with the proposed rule. This action will allow interested persons additional time to prepare and submit comments.

**DATES:** The comment period for the proposed rule published on October 27, 2016 (81 FR 74722) is reopened. We will consider all comments that we receive on or before February 16, 2017.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0022>.

- *Postal Mail/Commercial Delivery:* Send your comments to Docket No. APHIS–2016–0022, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0022> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30

p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Mr. David B. Lamb, Senior Regulatory Policy Specialist, USDA/APHIS/PPQ, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2103; [David.B.Lamb@aphis.usda.gov](mailto:David.B.Lamb@aphis.usda.gov).

**SUPPLEMENTARY INFORMATION:** On October 27, 2016, we published in the *Federal Register* (81 FR 74722–74727, Docket No. APHIS–2016–0022) a proposed rule to authorize the importation of Hass avocados from Colombia into the continental United States.

The pest risk assessment (PRA) that we used in order to draft the risk management document (RMD) associated with the rule, as well as the rule itself, considered *Maconellicoccus hirsutus* (Green), pink hibiscus mealybug, to be a pest of quarantine significance that could follow the pathway of Hass avocados from Colombia to the continental United States. However, this PRA was not the latest iteration that had been prepared. Rather, a subsequent iteration found that growing conditions for Hass avocados in Colombia, as well as standard packinghouse practices used in Colombia to prepare Hass avocados for export for commercial distribution, effectively preclude pink hibiscus mealybug from following the pathway of Hass avocados from Colombia to the continental United States.

We are making the more recent version of the PRA available for public review and comment, as well as a revised version of the RMD that reflects this change. Because there were no pink hibiscus mealybug-specific provisions in the proposed rule, however, we do not consider it necessary to modify the provisions of the proposed rule.

Comments on the proposed rule were required to be received on or before December 27, 2016. We are reopening the comment period on Docket No. APHIS–2016–0022 for an additional 30 days. We will also consider all comments received between December 28, 2016, and the date of this notice. This action will allow interested persons additional time to review the new PRA and RMD, and prepare and submit comments.

**Authority:** 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 9th day of January, 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2017–00672 Filed 1–13–17; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA–2016–9344; Airspace Docket No. 16–AEA–7]

#### Proposed Amendment of Class E Airspace, Atlantic City, NJ

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to amend Class E airspace at Atlantic City, NJ, as Atlantic City Municipal/Bader Field has closed, requiring airspace reconfiguration at Atlantic City International Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations Atlantic City International Airport.

**DATES:** Comments must be received on or before March 3, 2017.

**ADDRESSES:** Send comments on this proposal to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Bldg. Ground Floor, Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or 202–366–9826. You must identify the Docket No. FAA–2016–9344; Airspace Docket No. 16–AEA–7, at the beginning of your comments. You may also submit and review received comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed

on line at [http://www.faa.gov/air\\_traffic/publications/](http://www.faa.gov/air_traffic/publications/). For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202-267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202-741-6030, or go to [http://www.archives.gov/federal-register/code-of-federal-regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code-of-federal-regulations/ibr_locations.html).

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

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-6364.

#### **SUPPLEMENTARY INFORMATION:**

##### **Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Atlantic City International Airport, Atlantic City, NJ.

##### **Comments Invited**

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. You may also submit comments through the Internet at <http://www.regulations.gov>.

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2016-9344; Airspace Docket No. 16-AEA-7." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

##### **Availability of NPRMs**

An electronic copy of this document may be downloaded from and comments submitted through <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.regulations.gov>.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

##### **Availability and Summary of Documents for Incorporation by Reference**

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

##### **The Proposal**

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) Part 71 to amend Class E airspace designated as an extension to Class C surface area, and Class E airspace extending upward from 700 feet or more above the surface at

Atlantic City International Airport, due to the closing of Atlantic City Municipal/Bader Field from the airspace description as the airport has closed, no longer requiring controlled airspace.

Class E airspace designations are published in Paragraph 6003 and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

##### **Regulatory Notices and Analyses**

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

##### **Environmental Review**

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

##### **Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

##### **The Proposed Amendment**

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

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

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

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

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

*Paragraph 6003. Class E Airspace Designated as an Extension to a Class C Surface Area.*

\* \* \* \* \*

**AEA NJ E3 Atlantic City, NJ [Amended]**

Atlantic City International Airport, NJ  
(Lat. 39°27'27" N., long. 74°34'38" W.)  
Atlantic City VORTAC

(Lat. 39°27'21" N., long. 74°34'35" W.)

That airspace extending upward from the surface within 2.7 miles either side of the Atlantic City VORTAC 303° radial extending from the 5-mile radius to 7.4 miles northwest of Atlantic City International Airport.

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

\* \* \* \* \*

**AEA NJ E5 Atlantic City, NJ [Amended]**

Atlantic City International Airport, NJ  
(Lat. 39°27'27" N., long. 74°34'38" W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Atlantic City International Airport.

Issued in College Park, Georgia, on December 29, 2016.

**Debra L. Hogan,**

*Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2017-00302 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

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**DEPARTMENT OF HOMELAND SECURITY**
**U.S. Customs and Border Protection****DEPARTMENT OF THE TREASURY****19 CFR Part 133**

[USCBP-2016-0076]

RIN 1515-AE21

**Donations of Technology and Support Services To Enforce Intellectual Property Rights**

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes amendments to the U.S. Customs and Border Protection (CBP) regulations pertaining to the enforcement of

intellectual property rights. Specifically, CBP is proposing amendments to implement a section of the Trade Facilitation and Trade Enforcement Act of 2015 which requires CBP to prescribe regulatory procedures for the donation of technologies, training, or other support services for the purpose of assisting CBP in intellectual property enforcement. The proposed regulations would enhance CBP's intellectual property rights enforcement capabilities. **DATES:** Comments must be received on or before March 3, 2017.

**ADDRESSES:** You may submit comments, identified by *docket number*, by one of the following methods:

- Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the instructions for submitting comments via Docket No. USCBP-2016-0076.

- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229-1177.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229-1177. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

**FOR FURTHER INFORMATION CONTACT:** Garrett D. Wright, Chief, Donations Acceptance Program, Office of Field Operations, U.S. Customs and Border Protection, telephone (202) 344-2344.

**SUPPLEMENTARY INFORMATION:****Public Participation**

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. U.S. Customs and Border

Protection (CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rulemaking. Comments that will provide the most assistance to CBP will reference a specific portion of the proposed rulemaking, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change. See **ADDRESSES** above for information on how to submit comments.

**Background**

The Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), Public Law 114-125, 130 Stat. 122 (19 U.S.C. 4301 note), enacted February 24, 2016, includes an assortment of trade facilitation and trade enforcement provisions, including several that focus on improving CBP's intellectual property rights (IPR) enforcement at the border. Section 308(d) of the TFTEA requires the Commissioner of CBP to prescribe regulations that will enable CBP to receive donations of technologies, training, and other support services for the purpose of assisting CBP in detecting and identifying imports that infringe intellectual property rights.

In House Report 114-114, the House Ways and Means Committee stated that CBP should take steps to ensure that personnel dedicated to enforcement of IPR are effectively trained to detect and identify infringing imports. The Committee noted that much of the expertise in this area lies within the private sector, and that companies are most knowledgeable about their products and can provide valuable training to CBP on detection. H.R. 114-114 at 76.

**Discussion of Proposed Amendments**

*New Subpart H to Part 133—Donations of Intellectual Property Rights Technology and Support Services*

§ 133.61

This document proposes to implement section 308(d) of the TFTEA by promulgating a new subpart H to part 133 of title 19 of the Code of Federal Regulations, entitled "[D]onations of Intellectual Property Rights Technology and Support Services," which would provide for the receipt and acceptance by CBP of donations of hardware, software, equipment, and similar technologies, as well as training and support services, for the purpose of assisting CBP in enforcing IPR. It is also proposed to add and reserve subpart G to part 133.



New subpart H, as set forth in proposed new § 133.61, prescribes the methods by which donations of IPR technology and support services may be made. Specifically, proposed 19 CFR 133.61(a) sets forth the scope of this section and identifies the relevant authority. Proposed 19 CFR 133.61(b) prescribes the conditions applicable to a donation offer and provides that CBP will notify the donor, in writing, if additional information is requested or if CBP has determined that it will not accept the donation. In this regard, it is noted that CBP will take into consideration all aspects of the proposed donation offer, including whether such offer would pose a real or potential conflict between the interests of the donor and the interests of the government. Proposed 19 CFR 133.61(c) provides that if CBP elects to accept a donation offer, CBP will enter into a signed, written agreement with an authorized representative of the donating entity that commemorates all applicable terms and conditions, and that an agreement to accept training and other support services must provide that the services or training are offered without the expectation of payment and that the service provider expressly waives any future claims against the government.

#### Authority To Accept Donations

As noted above, pursuant to section 308(d) of the TFTEA, CBP is required to prescribe regulatory procedures for donations of hardware, software, equipment, and similar technologies, as well as training and support services, for the purpose of assisting CBP in enforcing IPR.

Acceptance of such donations must also be consistent with either section 482 of the Homeland Security Act of 2002, as amended by section 2 of the Cross-Border Trade Enhancement Act of 2016 (Pub. L. 114–279), or section 507 of the Department of Homeland Security Appropriations Act of 2004 (Pub. L. 108–90).

Section 482 of the Homeland Security Act replaced section 559 of Title V of Division F of the Consolidated Appropriations Act, 2014 (Pub. L. 113–76) and permits CBP, in consultation with the General Services Administration (GSA), to “enter into an agreement with any entity to accept a donation of personal property, money, or nonpersonal services” to be used for certain CBP activities at most ports of entry where CBP performs inspection services. Generally speaking, donations may be used for certain activities of CBP’s Office of Field Operations, including expenses related to “(A)

furniture, equipment, or technology, including the installation or deployment of such items; and (B) the operation and maintenance of such furniture, fixtures, equipment or technology.” Section 482(a)(3). To implement section 482, CBP will build upon its experience in implementing section 559 of Title V of Division F of the Consolidated Appropriations Act, 2014, where CBP and the GSA issued the *Section 559 Donation Acceptance Authority Proposal Evaluation Procedures & Criteria Framework* in October, 2014.<sup>1</sup> Pursuant to Section 482(c)(3), CBP in consultation with GSA will establish criteria for evaluating donation proposals under Section 482 and make such criteria publicly available.

Donations that may not be accepted under section 482 may be considered under section 507 of the DHS Appropriations Act of 2004. Section 507 of the DHS Appropriations Act of 2004 made the DHS Gifts and Donations account (formerly the Federal Emergency Management Agency “Bequests and Gifts” account) “available to the Department of Homeland Security . . . for the Secretary of Homeland Security to accept, hold, administer and utilize gifts and bequests, including property, to facilitate the work of the Department of Homeland Security.” Title V, Public Law 108–90, 117 Stat. 1153–1154. DHS policy on the acceptance of gifts pursuant to section 507 is contained in DHS Directive 112–02 and DHS Instruction 112–02–001. The Secretary of DHS delegated the authority to accept and utilize gifts to the heads of certain DHS components, including the Commissioner of CBP, in DHS Delegation 0006.

#### Executive Orders 13563 and 12866

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

<sup>1</sup> <https://www.cbp.gov/document/guidance/section-559-donation-acceptance-authority-proposal-evaluation-procedures-and>. Section 483 of the Homeland Security Act, as amended by the Cross-Border Trade Enhancement Act, also exempts from section 482 existing agreements entered into pursuant to section 559, as well as proposals already accepted for consideration by CBP.

proposed rule is not a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this regulation.

This rule proposes amendments to the CBP regulations that would prescribe procedures for the voluntary donation of technology, training, and other support services for the purpose of assisting CBP in enforcing IPR, as required by section 308(d) of the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114–125, 130 Stat. 122 (19 U.S.C. 4301 note). These donations would improve CBP’s knowledge of intellectual property and improve its ability to detect infringing articles and prevent their importation.

Because donations under this rule would be voluntary, CBP assumes that entities would only make donations if they believe it is in their best interest to do so. The cost of the donation itself, including any training provided, would vary greatly depending on the particulars of the donation. Due to a lack of data on the types of donations that entities would offer as a result of this rulemaking, CBP is unable to estimate the cost of these donations to the public. In addition to the cost of the donated product or training itself, donors would bear some paperwork related costs with this rule. Under this rule, if finalized, entities must submit an offer of a donation in writing to CBP and provide all pertinent details regarding the scope, purpose, expected benefits, intended use, estimated costs, and proposed conditions of the donation. Based on discussions with CBP’s Office of Field Operations, CBP estimates that approximately 50 entities would make donations annually and that there would be one donation made per entity annually, for a total of 50 donations per year. CBP estimates that it would take an entity approximately 2 hours to write the offer of donation. In most cases, CBP believes that attorneys either employed or hired by the donor would write the offer of donation. Considering the median hourly wage of an attorney of \$80.83,<sup>2,3</sup> writing the

<sup>2</sup> Source of median wage rate: U.S. Bureau of Labor Statistics, Occupational Employment Statistics, “May 2014 National Occupational Employment and Wage Estimates, United States—Median Hourly Wage by Occupation Code: 23–1011.” Updated March 25, 2015. Available at <http://www.bls.gov/oes/2014/may/oes231011.htm>. Accessed June 15, 2015. CBP adjusted this figure, which was in 2014 U.S. dollars, to 2015 U.S. dollars by applying a 1.0 percent annual growth rate to the figure, as recommended by the U.S. Department of Transportation’s value of travel time guidance. Source: U.S. Department of Transportation, Office of Transportation Policy. *The Value of Travel Time Savings: Departmental Guidance for Conducting*



offers of donation would result in a total annual time cost to donors of \$8,083 ( $\$80.83 * 2 \text{ hours} * 50 \text{ written donation proposals}$ ). This would equate to a cost of \$161.66 per entity. CBP again notes that this is a voluntary program, and entities would only provide donations if the benefits of doing so outweigh the costs.

In addition to donor costs, this rule would introduce a time cost to CBP to process each offer of donation. As with donor costs, CBP's cost to receive and learn about the donated article would depend on the particulars of the donation. Also, accepting the donation is voluntary on CBP's part and the agency would only accept the donation if it is in CBP's best interest to do so. In addition to CBP's costs associated with receiving and learning about the donated article, there are quantifiable costs to CBP related to evaluating the donation and making a decision on whether to accept it under the conditions provided. CBP estimates, at a minimum, the agency's evaluation time to be approximately 10 hours for each of the 50 donations made to CBP annually. CBP predicts that in most cases, each written offer of donation would be evaluated by five CBP employees. Based on the average hourly wage for a general CBP employee of \$55.91,<sup>4</sup> evaluating the 50 offers of donation each year would result in an annual time cost to CBP of \$139,775.00 ( $\$55.91 * 5 \text{ CBP employees} * 10 \text{ hours} * 50 \text{ written donation proposals}$ ). On

*Economic Evaluations Revision 2 (2015 Update)*, "Table 4 (Revision 2-corrected): Recommended Hourly Values of Travel Time Savings." April 29, 2015. <http://www.transportation.gov/sites/dot.gov/files/docs/Revised%20Departmental%20Guidance%20on%20Valuation%20of%20Travel%20Time%20in%20Economic%20Analysis.pdf>. Accessed June 1, 2016.

<sup>3</sup> The total compensation to wages and salaries ratio is equal to the calculated average of the 2014 quarterly estimates (shown under Mar., June, Sep., Dec.) of the total compensation cost per hour worked for Professional and Related occupations (49.69) divided by the calculated average of the 2014 quarterly estimates (shown under Mar., June, Sep., Dec.) of wages and salaries cost per hour worked for the same occupation category (34.315). Source of total compensation to wages and salaries ratio data: U.S. Bureau of Labor Statistics. Employer Costs for Employee Compensation. *Employer Costs for Employee Compensation Historical Listing March 2004–December 2015*, "Table 3. Civilian workers, by occupational group: employer costs per hours worked for employee compensation and costs as a percentage of total compensation, 2004–2015 by Respondent Type: Professional and related occupations." June 10, 2015. Available at <http://www.bls.gov/ncs/ect/sp/ceccqrtn.pdf>. Accessed June 15, 2015.

<sup>4</sup> CBP bases this wage on the FY 2015 salary and benefits of the national average of general, non-CBP Officer/frontline CBP positions, which is equal to a GS–12, Step 5. Source: Email correspondence with CBP's Office of Administration on June 25, 2015.

average, each offer of donation would cost CBP \$2,795.50 in evaluation time costs.

In summary, this rule could result in a total quantifiable annual cost to the public of \$8,083 and a total annual cost to CBP of \$139,775.00. Additionally, the public would bear a cost equal to the value of the donation and CBP would bear a cost to accept the donation. As these costs would vary depending on the particulars of the donation, CBP is unable to quantify them in this analysis. Because donations are voluntary for both the donor and CBP, donations would presumably only occur if the benefits to each party outweigh the costs.

Along with costs, the proposed rule would provide benefits to the donor and CBP. In particular, the proposed rule would enhance CBP's IPR enforcement capabilities by making donations of authentication devices, equipment, and training available to CBP personnel. This would help protect the entities making donations from the illegal importation of IPR-infringing products. The value of this benefit would vary depending on how much an entity believes IPR enforcement would improve because of its donation. As stated earlier, an entity would only make the donation if it believes the benefits of improved IPR enforcement outweigh the costs.

#### Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

This proposed rule, if finalized, would allow entities to voluntarily donate technology, training, and other support services to improve CBP's ability to enforce IPR potentially related to their goods. As any entity with intellectual property could make these donations, this rule may affect a substantial number of small entities. However, this rule imposes no new obligations on entities, including those considered small. Any small entity that chooses to make these donations would presumably do so because it believes the benefits of donating exceed the costs. Therefore, this rule would not have a significant economic impact on small

entities. Given these reasons, CBP certifies that this rule, if finalized, will not have a significant economic impact on a substantial number of small entities. CBP invites public comments on this determination.

#### Paperwork Reduction Act

An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

OMB approved collection 1651–0123 will be amended to reflect a new information collection proposed by this rule for written offers of donations to CBP of technology, training, and other support services in accordance with 19 CFR 133.61(b). CBP estimates that this rule would result in 50 responses each year and 100 burden hours to respondents annually. The new information collection would reflect the burden hours for each written offer of donation provided to CBP as follows:

*Estimated number of annual respondents:* 50.

*Estimated number of annual responses:* 50.

*Estimated time burden per response:* 2 hours.

*Estimated total annual time burden:* 100 hours.

#### Signing Authority

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

#### List of Subjects

19 CFR Part 133

Circumvention devices, Copying or simulating trademarks, Copyrights, Counterfeit goods, Customs duties and inspection, Detentions, Donations, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Technology, Trademarks, Trade names, Support services.

#### Proposed Amendments to Part 133 of the CBP Regulations

For the reasons set forth in the preamble, CBP proposes to amend 19 CFR part 133 as set forth below:

#### PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

■ 1. The general authority citation for part 133 continues, and the specific authority for new subpart H is added, to read as follows:

**Authority:** 15 U.S.C. 1124, 1125, 1127; 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1202, 1499, 1526, 1624; 31 U.S.C. 9701.

\* \* \* \* \*

Section 133.61 also issued under Sec. 308(d), Pub. L. 114–125; Sec. 507, Pub. L. 108–90; Sec. 2, Pub. L. 114–279.

### Subpart G—[Reserved].

- 2. Add and reserve subpart G.
- 3. Add subpart H, consisting of § 133.61, to read as follows:

### Subpart H—Donations of Intellectual Property Rights Technology and Support Services.

#### § 133.61 Donations of intellectual property rights technology and support services.

(a) *Scope.* The Commissioner of U.S. Customs and Border Protection (CBP) is authorized to accept donations of hardware, software, equipment, and similar technologies, as well as donated support services and training, from private sector entities, for the purpose of assisting CBP in enforcing intellectual property rights. Such acceptance must be consistent with the conditions set forth in this section and section 308(d) of the Trade Facilitation and Trade Enforcement Act of 2015, as well as either section 482 of the Homeland Security Act of 2002 or section 507 of the DHS Appropriations Act of 2004.

(b) *Donation offer.* A donation offer must be submitted to CBP either via email, to [IPRdonations@cbp.dhs.gov](mailto:IPRdonations@cbp.dhs.gov), or mailed to the attention of the Executive Assistant Commissioner, Office of Field Operations, or his/her designee. The donation offer must describe the proposed donation in sufficient detail to enable CBP to determine its compatibility with existing CBP technologies, networks, and facilities (e.g. operating system or similar requirements, power supply requirements, item size and weight, etc.). The donation offer must also include information pertaining to the donation's scope, purpose, expected benefits, intended use, costs, and attached conditions, as applicable, that is sufficient to enable CBP to evaluate the donation and make a determination as to whether to accept it. CBP will notify the donor, in writing, if additional information is requested or if CBP has determined that it will not accept the donation.

(c) *Agreement to accept donation.* If CBP accepts a donation of hardware, software, equipment, technologies, or to accept training and other support services, for the purpose of enforcing intellectual property rights, CBP will enter into a signed, written agreement with an authorized representative of the

donor. The agreement must contain all applicable terms and conditions of the donation. An agreement to accept training and other support services must provide that the services or training are offered without the expectation of payment, and that the service provider expressly waives any future claims against the government.

**R. Gil Kerlikowske,**  
*Commissioner.*

Approved: January 09, 2017.

**Timothy E. Skud,**  
*Deputy Assistant Secretary of the Treasury.*  
[FR Doc. 2017–00653 Filed 1–13–17; 8:45 am]

BILLING CODE 9111–14–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 117

[Docket No. FDA–2008–D–0096 (Formerly Docket No. 2007D–0494)]

#### Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Revised Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a revised draft guidance for industry entitled “Control of *Listeria monocytogenes* in Ready-To-Eat Foods.” The revised draft guidance is intended for any person who is subject to our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” and who manufactures, processes, packs, or holds ready-to-eat (RTE) foods. The revised draft guidance is intended to help such persons comply with the requirements of that regulation with respect to measures that can significantly minimize or prevent the contamination of RTE food with *L. monocytogenes* whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *L. monocytogenes*) that would significantly minimize *L. monocytogenes*.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we issue the final version of the

guidance, submit either electronic or written comments on the draft guidance by July 26, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2008–D–0096 for “Control of *Listeria monocytogenes* in Ready-To-Eat Foods.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the revised draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-300), 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a revised draft guidance for industry entitled "Control of *Listeria*

*monocytogenes* in Ready-To-Eat Foods." We are issuing the revised draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of February 7, 2008 (73 FR 7293), we made available a draft guidance for industry entitled "Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods" (the 2008 draft *Listeria* guidance). The recommendations in the 2008 draft *Listeria* guidance were intended to complement the requirements in a regulation entitled "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food," which had been established in part 110 (21 CFR part 110). The recommendations in the 2008 draft *Listeria* guidance also were intended to assist processors of refrigerated and frozen RTE foods in meeting the requirements in part 110 with respect to the control of *L. monocytogenes*. We gave interested parties an opportunity to submit comments by April 7, 2008, for us to consider before beginning work on the final version of the guidance. We received several comments on the 2008 draft *Listeria* guidance.

Since issuing the 2008 draft *Listeria* guidance, we conducted rulemaking to amend the current good manufacturing practice (CGMP) requirements in part 110 to modernize them and establish them in new part 117 (21 CFR part 117), subparts A, B, and F (80 FR 55908, September 17, 2015). Part 117 (entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food") also includes new requirements (in subparts A, C, D, E, F, and G) for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The new human food preventive controls requirements are part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). We also discussed certain recommendations in the 2008 draft *Listeria* guidance with our Food Advisory Committee during a meeting

held on December 7 and 8, 2015 (80 FR 69229, November 9, 2015 and Ref. 1).

We have revised the 2008 draft *Listeria* guidance to reflect the comments we received on that draft guidance, the amended CGMP requirements now established in part 117, the new human food preventive controls requirements established in part 117, and the recommendations of our Food Advisory Committee (Ref. 2). The revised draft guidance is intended to explain our current thinking on procedures and practices to help food establishments that are subject to part 117 to: (1) Comply with the CGMP requirements of part 117 (e.g., for personnel, buildings and facilities, equipment and utensils, and production and process controls) during the production of an RTE food that is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *L. monocytogenes*) that would significantly minimize *L. monocytogenes*; and (2) comply with certain human food preventive controls requirements regarding environmental pathogens in such RTE foods.

Part 117 defines "environmental pathogen" to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen (21 CFR 117.3). Within that definition, *L. monocytogenes* is listed as an example of an environmental pathogen. The hazard analysis required by part 117 must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen (§ 117.130(c)(1)(ii)). If the hazard analysis identifies *L. monocytogenes* as a hazard requiring a preventive control, the facility must identify one or more preventive controls to provide assurances that *L. monocytogenes* will be significantly minimized or prevented in the facility's food products and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (§ 117.135(a)). In addition, the human food preventive controls requirements specify that, as appropriate to the facility, the food, and

the nature of the preventive control and its role in the facility's food safety system, the facility must conduct activities that include environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples (§ 117.165(a)(3)). The revised draft guidance includes recommendations for controls to significantly minimize or prevent *L. monocytogenes* in RTE foods, for sanitation controls to eliminate *L. monocytogenes* from the food production environment, and for environmental monitoring as verification of sanitation controls.

## II. Paperwork Reduction Act of 1995

The revised draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB Control No. 0910–0751.

FDA tentatively concludes that the revised draft guidance also contains proposed information collection provisions that are subject to review by OMB under the PRA but are not included in the information collection approved under OMB Control No. 0910–0751. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register**.

## III. Electronic Access

Persons with access to the Internet may obtain the revised draft guidance at either <http://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

## IV. References

The following references are on display at the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA. 2015. Food Advisory Committee Meeting, Charge and Questions. Topic: Addressing *Listeria monocytogenes* in Ready-To-Eat Foods, December 7–8, 2015. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM472842.pdf>.
2. FDA. 2015. Food Advisory Committee (FAC) Recommendations. Topic: Addressing *Listeria monocytogenes* in Ready-To-Eat Foods, December 7–8, 2015. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM476521.pdf>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–00819 Filed 1–13–17; 8:45 am]

**BILLING CODE 4164–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 141 and 143

[EPA–HQ–OW–2015–0680; FRL–9958–23–OW]

RIN 2040–AF55

### Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) proposes to make conforming changes to existing drinking water regulations based on the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). Section 1417 of the Safe Drinking Water Act (SDWA) prohibits the use and introduction into commerce of certain plumbing products that are not lead free. The RLDWA revised the definition of lead free to lower the allowable maximum lead content from 8.0 percent to a weighted average of 0.25

percent of the wetted surfaces of plumbing products and established a statutory method for calculating lead content. In addition, the RLDWA created exemptions from the lead free requirements for plumbing products that are used exclusively for nonpotable services as well as for other specified products. The CFSA further amended section 1417 to exempt fire hydrants from these requirements.

EPA proposes to establish new requirements to assure that individuals purchasing, installing or inspecting potable water systems can identify lead free plumbing materials. Specifically, EPA proposes to establish labeling requirements to differentiate plumbing products that meet the lead free requirements from those that are exempt from the lead free requirements and to require manufacturers to certify compliance with the lead free requirements. These proposed requirements would reduce inadvertent use of non-lead free plumbing products in potable use applications and, consequently, reduce exposure to lead in drinking water and associated adverse health effects.

**DATES:** Comments must be received on or before April 17, 2017.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OW–2015–0680, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system).

For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Russ Perkinson, telephone number: 202–564–4901; email address: [perkinson.russ@epa.gov](mailto:perkinson.russ@epa.gov), Office of Ground Water and Drinking Water, Standards and Risk

Management Division (4607), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

#### SUPPLEMENTARY INFORMATION:

#### Abbreviations and Acronyms

AFS—American Foundries Society  
ANSI—American National Standards Institute  
CFSA—Community Fire Safety Act of 2013  
CFR—Code of Federal Regulations  
FAQs—Frequently Asked Questions  
O&M—Operations and Maintenance  
NAICS—North American Industry Classification System  
NSF—NSF International  
PMI—Plumbing Manufacturers International  
RFA—Regulatory Flexibility Act  
RLDWA—Reduction of Lead in Drinking Water Act of 2011  
SDWA—Safe Drinking Water Act  
SIC—Standard Industrial Classification  
UL—Underwriters Laboratories

#### Table of Contents

- I. General Information
  - A. Does this action apply to me?
  - B. What action is EPA taking?
  - C. What is EPA's authority for taking this action?
  - D. What are the costs and benefits of this action?
- II. Background
- III. Summary of Data Used
  - A. Characterization of the Affected Industry
  - B. Determining Baseline Industry Practices and Potential Costs of Compliance
- IV. Proposed Regulatory Provisions
  - A. Scope/Applicability of Proposed Rule
  - B. Labeling of Potable Use Products
  - C. Exempt Products
  - D. Product Certification
  - E. Other Regulatory Requirements and Clarifications
  - F. Implementation
- V. Costs
  - A. Initial Administrative and Initial Implementation Costs
  - B. Labeling Potable Use Products
  - C. Labeling Products Eligible for the "Used Exclusively" Exemption
  - D. Product Certification
  - E. Response to EPA Data Request Costs
  - F. Other Regulatory Requirements and Clarifications
- VI. Economic Impacts Analysis
  - A. Annualized Social Costs Estimates
  - B. Economic Impacts—Cost-to-Revenue Analysis
- VII. Benefits
- VIII. Statutory and Executive Orders Reviews
- IX. References

#### I. General Information

##### A. Does this action apply to me?

The statutory prohibitions on use and introduction into commerce of certain products that are not lead free codified by this rule apply to "any person" as defined in the Safe Drinking Water Act (SDWA). This rule implementing those provisions applies to any person who

would introduce plumbing products into commerce, such as manufacturers, importers, wholesalers, distributors, resellers, retailers, and to any person who would use plumbing products in a public water system or in a residential or non-residential facility providing water for human consumption. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

##### B. What action is EPA taking?

EPA is proposing this regulation to codify revisions to the SDWA prohibition on use and introduction into commerce of certain products that are not lead free (hereafter termed the SDWA lead prohibitions) as enacted in the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). EPA is also proposing requirements to certify and label plumbing products introduced into commerce to assure they are lead free.

SDWA 1417(a)(1) prohibits the "use of any pipe, any pipe or plumbing fitting or fixture, any solder, or any flux in the installation or repair of any public water system; or any plumbing in a residential or non-residential facility providing water for human consumption, that is not lead free" as defined in section 1417(d). Section 1417(a)(3) provides that "it shall be unlawful (A) for any person to introduce into commerce any pipe, or any pipe or plumbing fitting or fixture, that is not lead free, except for a pipe that is used in manufacturing or industrial processing; (B) for any person engaged in the business of selling plumbing supplies, except manufacturers, to sell solder or flux that is not lead free; or (C) for any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption."

The 2011 RLDWA revised section 1417 to redefine lead free in SDWA section 1417(d) to lower the maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of plumbing products; established a statutory method for the calculation of lead content; and eliminated the requirement that lead free products be in compliance with voluntary standards established in accordance with SDWA 1417(e) for leaching of lead from new plumbing fittings and fixtures. In addition, the

RLDWA created exemptions in SDWA section 1417(a)(4) from the prohibitions on the use or introduction into commerce for "pipes, pipe fittings, plumbing fittings, or fixtures, including backflow preventers, that are used exclusively for nonpotable services such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption" (SDWA 1417(a)(4)(A)), as well as for "toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, service saddles, or water distribution main gate valves that are 2 inches in diameter or larger." (SDWA 1417(a)(4)(B)). The CFSA further amended section 1417 to exempt fire hydrants.

In addition to codifying the revised requirements under RLDWA and CFSA, EPA is proposing product certification requirements and data gathering authorities to ensure consistent implementation and enforcement of the SDWA lead prohibition, as well as new labeling requirements to assure that individuals purchasing, installing or inspecting potable water systems can identify lead free plumbing materials. Specifically, EPA proposes to establish labeling requirements to differentiate plumbing products that meet the lead free requirements from those that are exempt from the lead free requirements and to require manufacturers to certify compliance with the lead free requirements. These proposed requirements would reduce inadvertent use of non-lead free plumbing products in potable use applications and, consequently, reduce exposure to lead in drinking water and associated adverse health effects.

The goals of these proposed regulatory provisions are to limit accidental lead exposure by clearly identifying those products to be used or not used for potable services; and to ensure that plumbing products that are identified as lead free for use in potable services meet the requirements of the SDWA lead prohibition.

##### C. What is EPA's authority for taking this action?

EPA's authority for this proposed rule is sections 1417, 1445 and 1450 of the SDWA, 42 U.S.C. 300j-6, 300j-4, and 300j-9. SDWA section 1417 authorizes the EPA Administrator to "prescribe such regulations as are necessary or appropriate to carry out his/her functions under this subchapter." EPA's current regulations (40 CFR 141.43) codify parts of section 1417 of the SDWA, but they do not reflect the current version of section 1417, as

amended by the RLDWA and the CFSA. This proposed rule would amend those regulations to reflect the current law. In addition, because the RLDWA created exemptions from the use prohibition in section 1417(a)(1) and the introduction into commerce prohibition in section 1417(a)(3), EPA proposes additional regulations to aid in the implementation and enforcement of these prohibitions.

#### *D. What are the costs and benefits of this action?*

EPA conducted an incremental compliance cost analysis of this proposed rule. For detail on the cost analysis see sections V and VI of this notice. The Technical Support Document (USEPA, 2016) prepared for this proposed rule and available in the docket for this proposed rule contains the detailed description of the cost assessment. EPA did not conduct a quantified and monetized benefits analysis, but a qualitative discussion of the benefits attributable to this rule can be found in section VII and in the Technical Support Document.

Total annualized costs for the proposed rule range from \$12 million discounted at three percent to \$18 million discounted at seven percent. These costs include administrative requirement costs, the cost to potable use product manufacturers for both labeling on the product and on the product's packaging, the cost to manufacturers employing the "used exclusively" exemption for package labeling indicating non-potable uses, third party and self-certification costs and the costs of responding to EPA data requests.

The proposed rule would reduce inadvertent use of non-lead free plumbing products in potable use applications and, as a result, would reduce exposure to lead in drinking water. The benefits of this proposed rule would be the resulting incremental reduction in the adverse health effects of low doses of lead, which include adverse neurological, cardiovascular, renal, reproductive, developmental, immunological and carcinogenic effects.

## **II. Background**

Lead can be introduced into drinking water by corrosion of plumbing products (pipes, pipe and plumbing fittings and fixtures, solder, and flux). Lead exposure causes damage to the brain and kidneys, and can interfere with the production of red blood cells that carry oxygen to all parts of the body. The greatest risk associated with lead exposure is to infants, young children and pregnant women. Scientists have linked the effects of lead

on the brain with lowered IQ in children.

In 1986, Congress amended the SDWA to prohibit the use of pipes, solder or flux that are not "lead free" in public water systems or plumbing in facilities providing water for human consumption. At the time, lead free was defined as solder and flux with no more than 0.2 percent lead and pipes with no more than 8.0 percent lead.

In 1996, Congress further amended the SDWA to prohibit the use of pipe and plumbing fittings and fixtures that are not lead free in the installation and repair of any public water system or plumbing in a facility providing water for human consumption. The 1996 amendments also required lead free plumbing fittings and fixtures (endpoint devices) to be in compliance with a lead leaching standard established in accordance with section 1417(e).

The 1996 amendments also made it unlawful for any person to introduce into commerce any pipe, pipe or plumbing fitting, or fixture that is not lead free, except for a pipe that is used in manufacturing or industrial processing. As amended in 1996, SDWA section 1417(a)(3)(B) prohibits "any person engaged in the business of selling plumbing supplies, except manufacturers, to sell solder or flux that is not lead free," and SDWA section 1417(a)(3)(C) makes it unlawful "for any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing of water for human consumption."

In 2011, Congress enacted the RLDWA. It revised the definition of lead free by lowering the allowable maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of plumbing products. It also revised the definition of lead free to include a statutory method for the calculation of lead content, and eliminated the requirement that lead free products be in compliance with standards established in accordance with SDWA section 1417(e) for leaching of lead from new plumbing fittings and fixtures.

The 2011 RLDWA also established two types of exemptions from the section 1417 prohibitions on the use or introduction into commerce of pipes, pipe fittings, plumbing fittings or fixtures, solder or flux not meeting the statutory definition of lead free. One exemption is for pipes, pipe fittings, plumbing fittings or fixtures, including backflow preventers, that are used exclusively for non-potable services,

such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption (SDWA 1417(a)(4)(A)). A second exemption was established for toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, service saddles, or water distribution main gate valves that are 2 inches in diameter or larger (SDWA 1417(a)(4)(B)). The RLDWA established a prospective effective date of January 4, 2014, which provided a three-year timeframe for affected parties to transition to the new requirements. The CFSA further amended SDWA section 1417 to exempt fire hydrants from the prohibitions otherwise applicable under that section.

In anticipation of these changes taking effect, EPA provided a summary of the requirements of the lead ban provisions in SDWA section 1417 and answers to frequently asked questions (FAQs) related to the amendments to assist manufacturers, retailers, plumbers and consumers in understanding the changes to the law (USEPA, 2013a). In this FAQ document, EPA stated its intention to further evaluate and refine the issues raised in the FAQ in a future rulemaking.

## **III. Summary of Data Used**

### *A. Characterization of the Affected Industry*

A number of data sources were used in the characterization of the plumbing manufacturing industry. GMP Research, Inc., provided a report to EPA in 2014, which included data on the total number of both potable and non-potable plumbing products sold in 2013, distributed across 40 product subcategories, and the market share of the leading suppliers by each product subcategory that may be subject to EPA's proposed rule. These data were supplemented with information from a number of additional sources. Dun & Bradstreet data were obtained for those firms that were identified by North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) code classifications as potentially producing plumbing products that would be affected by the proposed rule. Additional data for plumbing manufacturers and fabricators were obtained from ThomasNet, a comprehensive online database that provides information on manufacturing firms in the United States. EPA also used NSF International's Certified Drinking Water System Components database, which provides a list of manufacturers who use NSF to certify

their products to NSF/ANSI Standard 61, including the subset of products that are certified to Annex G of that standard. Additional information was gathered from the Plumbing Manufacturers International (PMI) Web site, a plumbing industry trade association. EPA used data on the number of employees and annual receipts for firms from the U.S. Census Bureau's Statistics of U.S. Businesses.

Information used in the development of industry production growth was obtained from both the GMP Research, Inc., report and projections on United States housing growth from IHS Global Insight. The Technical Support Document (USEPA, 2016) contains more information and data sources used and is available in the docket.

#### *B. Determining Baseline Industry Practices and Potential Costs of Compliance*

EPA conducted calls with representatives of both the PMI and the American Foundries Society (AFS) industry associations and held a stakeholder webinar in 2015 in order to obtain information on current practice within the plumbing parts manufacturing industry, in regard to labeling of product packages, marking of the plumbing products themselves, and the technical feasibility and costs associated with making changes to product labeling and marking. Additionally, the two industry associations provided information to EPA on product identification methods, including the estimated percentage of products that currently include lead free identification and general cost information for modifications to package labeling and product marking. Information on the feasibility and time requirements for changing production molds in response to potential regulatory requirements was also discussed, along with plumbing product inventory turnover rates. The trade associations also provided information on the use and costs of third party certification in the industry.

In addition, data were obtained from a number of independent geographically diverse tool and dye firms on the cost of mold modifications. EPA also contacted suppliers to obtain capital equipment and operations and maintenance (O&M) costs to allow the Agency to estimate the economic impact of potential new labeling requirements under the proposed rule. EPA also contacted the eight firms currently accredited to certify plumbing components for compliance with NSF/ANSI Standard 372, for information on the cost of certification and the

technical process for testing and certifying products as meeting the standard.

#### **IV. Proposed Regulatory Provisions**

##### *A. Scope/Applicability of Proposed Rule*

The statutory prohibition on the use or introduction into commerce of pipes, pipe and plumbing fittings, fixtures, solder and flux that are not lead free, and the corresponding requirements described in this proposal would apply to any person. "Person" is defined under the SDWA to include individuals; corporations; companies; associations; partnerships; municipalities; or state, federal or tribal agencies. The statutory ban on selling solder and flux that is not lead free applies only to "any person engaged in the business of selling plumbing supplies." The use prohibition applies only to use in the "installation or repair" of any public water system or any plumbing in a residential or nonresidential facility or location that provides water for human consumption.

EPA solicits comments on all aspects of the proposed approach set forth in this notice. EPA specifically solicits comments, information and data on the following topics:

1. In order to clarify the requirements, set forth in the RLDWA and this proposal, EPA defined terms, such as "pipes," "fittings," "fixtures," "solder," "flux" and several subcategories of these components, which are terms used in the statute, but are not defined within section 1417 of the SDWA. EPA included these and other definitions to provide clarity to provisions of the proposed rule. EPA requests comment concerning the appropriateness of these definitions and any additional terms that should be defined, specifically terms describing exempt products included in section 1417(a)(4)(B) of the SDWA (e.g., water distribution main gate valve).

2. Section 1461 of the SDWA defines lead free with respect to drinking water coolers to mean that "each part or component of the cooler which may come into contact with drinking water contains no more than 8 percent lead" except that any solder, flux or storage tank interior surface may not contain more than 0.2 percent lead. SDWA section 1461(2) also authorizes the Administrator to establish more stringent requirements for treating any part or component of a drinking water cooler as lead free "whenever he determines that any such part may constitute an important source of lead in drinking water." A drinking water cooler is also a "fixture" under section

1417 of the SDWA; and, therefore, subject to the definition of lead free in section 1417. To give effect to both provisions, in practice, drinking water coolers would need to comply with the most restrictive of the requirements in sections 1417 and 1461 of the SDWA. For clarity, EPA could consider addressing the requirements of section 1461 in the final rule by inserting language such as: "In addition to the definitions of "lead-free" in § 143.12(a)(1) and (2), no drinking water cooler which contains any solder, flux, or storage tank interior surface which may come into contact with drinking water is lead free if the solder, flux, or storage tank interior surface contains more than 0.2 percent lead. Drinking water coolers must be manufactured such that each individual part or component that may come into contact with drinking water shall not contain more than 8 percent lead while still meeting the maximum 0.25 percent weighted average lead content of the wetted surfaces of the entire product." Should EPA consider adding such a provision to the rule?

3. The regulatory modifications in this proposal are designed, in part, to make the requirements set forth in section 1417 of the SDWA clearer and easier to implement and enforce in a consistent manner. Are additional clarifications needed to improve the regulation? If so, what specific clarifications are needed?

##### *B. Labeling Potable Use Products*

EPA evaluated several options concerning labeling of products that comply with the definition of lead free, including a requirement to label a product's packaging, physically marking a product, or a combination of both. EPA found that many manufacturers already utilize a combination of package and product labeling to inform product users that the products comply with the RLDWA and several similar state laws. In an effort to reduce consumer confusion and establish a consistent labeling scheme for these products, EPA proposes to require that all lead free products be labeled on the package, container or tag, as well as marked directly on the product, unless the product is too small for a legible marking (in a type approximately 8 point to 14 point depending on the method of marking and roughness of product surface). Direct product marking to indicate lead free status will assist building inspectors in verifying that installations are in compliance with plumbing codes and allow for identification of products if they become separated from packaging prior to installation. Separation from



packaging is likely to occur when used products are salvaged and sold or reused. After a product has been installed, a marking on the product itself will aid inspectors in identifying products that are lead free. In the long term, product marking to indicate lead free status will help the metals recycling industry segregate scrap materials that may be used to produce future products with low lead content.

This proposal provides that products that are too small to be marked on the product would be exempt from product marking, but would still need to comply with package, container or tag labeling. Also, when marking a product directly, the manufacturer should, to the extent practical, locate the marking in an area where it would be visible after installation. For those products where visual aesthetics is a factor in marketing and selling the product, the manufacturer may locate the marking in a manner that will not negatively impact the design.

EPA is not proposing a specific phrase be required on products or packages, but rather a performance standard that the phrase clearly conveys to users that the product is in compliance with the lead free requirements of the SDWA. The proposed regulation would include these examples of acceptable phrases for packaging: "This product conforms to the lead free requirements of the SDWA," or "Lead Free." Examples of acceptable product markings include: "Lead Free," "LF," or appropriate third party certification markings such as NSF/ANSI 372.

The requirements EPA proposes for lead free products will ensure that purchasers of plumbing products do not inadvertently use products that are not lead free, or re-introduce them into commerce for potable applications (e.g., in the case of a distributor, wholesale supplier, retailer). In addition to the package and product labeling requirement set forth in this proposal, EPA also considered requiring that either the product be marked or the package be labeled, but not both. While this option would decrease the costs and burden on the manufacturer responsible for labeling and marking, EPA is concerned that this option may not provide consumers and others (such as building inspectors) with the information needed to determine that a product is lead free after its initial purchase and installation. If a product is removed from its packaging and stored prior to installation, or if a regulatory body is looking for confirmation after installation that the product meets the lead free requirements, the package labeling would likely be insufficient.

Similarly, labeling of a product that is sold in an unlabeled package could also lead to the inadvertent installation of products that did not meet the new definition of lead free for potable purposes. For those reasons, labels on both the package and product are more appropriate (unless the product is too small for a label).

EPA solicits comments on all aspects of the proposed approach set forth above. In addition, EPA specifically solicits comments, information and data on the following topics:

1. Whether the rule should require the specific phrase "lead free" on package labeling and product markings rather than allowing some discretion in the use of phrases.

2. Whether an alternative specific phrase should be required for product and package labeling and, if so, what phrase.

3. If a specific phrase such as "lead free" were required, what period of time should be allowed for a transition period to enable manufacturers to modify their product and packaging to incorporate such phrase?

4. If products were required to use a specific phrase such as "lead free," whether that specific phrase should be required on both the package label and product marking or whether an abbreviated message should instead be allowed on the product.

5. Whether the rule should allow for either package labeling or product marking rather than package labeling and product marking.

6. Whether the rule should require any package labeling or product marking.

### C. Exempt Products

As a result of the exemptions created by the RLDWA, there will be plumbing products in the marketplace that are not required to meet the definition of lead free in section 1417(d) of the SDWA. Therefore, without appropriate labeling, there is a risk that non-lead free products will be inadvertently used in potable water applications or re-introduced into commerce for potable applications. There are several points along the distribution chain where EPA anticipates a non-lead free product could be mistakenly identified as a lead free product, including the initial sale of the product and at the time of installation.

Prior to the RLDWA, all plumbing devices were required to contain less than 8.0 percent lead, and certain endpoint devices (e.g., faucets) were required to meet additional standards for lead leaching. The exemptions created in the RLDWA allow for certain

pipes, fittings and fixtures to be sold with no limit to the amount of lead they contain.

One of the exemptions allows the use and introduction into commerce of pipes, fittings and fixtures that are used exclusively for nonpotable services. EPA has determined that a plumbing product that is physically incompatible with potable drinking water systems, rendering it impossible to be used for potable service, qualifies for this exemption.

In addition, EPA also proposes a second option for manufacturers to demonstrate that their product is "used exclusively" for nonpotable services and therefore eligible for this exemption (hereafter referred to in this notice as the "used exclusively" exemption). As EPA explained in the RLDWA FAQs, EPA would generally consider pipes, fittings or fixtures to be used exclusively for nonpotable services if they are marketed and sold for use in nonpotable services, and prominently and clearly labeled as illegal for use in potable services and not anticipated for use with water for human consumption. This proposal would codify that interpretation of this exemption by allowing the use of a package label (or the product marking for those products sold without an external package) clearly identifying the product as not for use with water for human consumption. A package label, combined with the labeling requirements for products that must meet the lead free requirements (i.e., package labeling and product marking described in section VI.B of this document and described in § 143.17 of this proposed rule), should provide consumers with sufficient information to determine which plumbing products are designed for use with potable water systems; thus significantly reducing the likelihood of improperly installing a non-lead free product.

The products specifically listed as exempt in SDWA section 1417(a)(4)(B) would not be subject to these labeling requirements or any of the other requirements of this proposal. These products are exempt from the requirements of this proposal: Toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, fire hydrants, shower valves, service saddles or water distribution main gate valves that are 2 inches in diameter or larger.

In addition to the specific plumbing devices excluded in the SDWA, EPA is also proposing to exclude clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps and emergency drench showers, because EPA is not aware of any potable use for these specific products.



EPA solicits comments on all aspects of the proposed approach set forth above. EPA specifically solicits comments, information and data on the following topics:

1. This proposal includes two methods of qualifying for the “used exclusively for non-potable exemption:” (a) the product is physically incompatible with potable water systems, or (b) the packaging is clearly labeled that it is not for use for water for human consumption. Are the criteria listed above appropriate for qualifying for the “used exclusively” exemption or are there different or additional criteria that EPA should consider?

2. Is there any reason EPA should not extend the used exclusively for non-potable services exemption to plumbing products that are physically compatible with drinking water systems?

3. Will labeling the packaging of pipes, fittings or fixtures as not for use for water for human consumption be sufficient to inform consumers of the appropriate use of the product?

4. In addition to the specific plumbing devices excluded in the SDWA, EPA is also proposing to exclude clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps and emergency drench showers. EPA is not aware of a potable use for these devices, or of a potable use product that they could be confused with; and as such, requiring a label to qualify for the “used exclusively” exemption could be redundant and unnecessary for those devices. Is EPA’s assumption about the lack of a potable use for these specific plumbing devices appropriate?

5. Are there other specific plumbing devices for which there are no potable uses, nor a potable use product they could be confused with that should be added to the list of excluded products?

6. EPA is proposing to retain the exemption for leaded joints used in the repair of cast iron pipes. EPA interprets the introduction into commerce provision as not prohibiting the sale or distribution of lead which may be used to form leaded joints used in the repair of cast iron pipes. Congress did not remove the statutory exemption for these types of repairs in section 1417(a)(1)(B) in either the 1996 or the 2011 amendments to section 1417 of the SDWA. Therefore, EPA believes that Congress intended to continue to allow the use of leaded joints necessary for the repair of cast iron pipes. EPA is seeking comment on this interpretation of section 1417(a)(1)(B).

#### D. Product Certification

EPA is proposing certification requirements for manufacturers and importers to demonstrate the maximum lead content of the wetted surfaces of their plumbing products do not exceed a weighted average of 0.25 percent using the method for the calculation of lead content established in the statute by either third party certification bodies or self-certification. For products that are required to meet Section 1417’s lead free requirements, EPA proposes to require manufacturers with 100 or more employees or importers representing foreign manufacturers with 100 or more employees to demonstrate compliance with the lead free definition by obtaining third party certification by an American National Standards Institute (ANSI) accredited third party certification body. EPA proposes to require manufacturers with fewer than 100 employees or importers representing foreign manufacturers with fewer than 100 employees to demonstrate compliance either through third party certification by an ANSI accredited certification body or through self-certification as described below.

Third party certification is currently required for certain products in widely adopted model plumbing codes. The most recent version of the single most widely adopted model plumbing code requires pipe, pipe fittings, joints, valves, faucets and fixture fittings used to supply water for drinking or cooking purposes to comply with the NSF/ANSI 372 standard for lead content. To meet the NSF/ANSI 372 standard, a product must be evaluated by an ANSI accredited third party certification body. These are independent organizations that test a product, review a product’s manufacturing process and determine that the product complies with specific standards for safety, quality, sustainability or performance (i.e., NSF/ANSI 372 standard for lead content). ANSI accredited third party certification bodies currently include NSF International, CSA Group, ICC Evaluation Services, International Association of Plumbing and Mechanical Officials Research & Testing (IAPMO R&T), Intertek Testing Services, Truesdail Laboratories, Underwriters Laboratories and Water Quality Association.

For manufacturers with fewer than 100 employees and importers sourcing products from or representing foreign manufacturers with fewer than 100 employees, the proposed rule provides the flexibility of allowing these entities to demonstrate product compliance by either using an ANSI accredited third

party certification body or by self-certification of the products. EPA estimated that manufacturers of covered products having fewer than 100 employees account for 72 percent of the total number of such manufacturers, but only produce 5 to 18 percent of the total volume of products. Small manufacturers that opt for the self-certification option would be required to develop a “certificate of conformity,” also known as a declaration of conformity, to attest that products meet the lead free requirements. A similar concept is currently in use for certain products regulated by the Federal Communications Commission and the Consumer Products Safety Commission. For manufacturers or importers electing to self-certify products, the proposed rule would require the manufacturer to post the certificate of conformity on a Web page with continuing public access in the United States.

As proposed, the certificate of conformity would be required to include: Contact information for the manufacturer and any importer, a listing of products, statements attesting that the products meet the lead free requirements and that the manufacturer’s or importer’s eligibility to self-certify the product is consistent with the regulation (i.e., manufacturer has fewer than 100 employees), a statement indicating how the manufacturer or importer verified conformance, and signatory information. The statement indicating how the manufacturer or importer verified conformance could be a brief overview of the general methodology employed, such as: Laboratory testing using X-Ray Fluorescence, other specific technologies, or that all source materials used in manufacture were confirmed to be less than 0.25 percent lead. This proposal would require manufacturers or importers using self-certification to maintain sufficient documentation to confirm that products meet the lead free requirements.

The proposed certification requirements will further reduce the likelihood that non-lead free products will either intentionally or inadvertently be placed into commerce or used in the repair or installation of any public water system or any plumbing in a facility providing water for human consumption. In addition, the labeling and the certification requirements will assist in the enforcement of the SDWA section 1417(a)(3) prohibition of the introduction into commerce of pipes, pipe or plumbing fittings or fixtures that are not lead free. A third party certification requirement leverages the

resources of the third party certifiers as well as the supply chain to help the market meet the requirements of RDLWA. The self-certification requirement, which is applicable to manufacturers with fewer than 100 employees, while not as rigorous as a requirement to obtain third party certification, nonetheless provides an additional assurance that products sold by those smaller manufacturers are lead free.

As an alternative to the proposed product certification requirements previously described, EPA considered requiring all manufacturers to obtain third party certification for products required to meet the lead free requirements. A uniform third party certification requirement would result in a level playing field for all manufacturers and would also make the marketplace consistent when a consumer is shopping for pipes, fittings or fixtures. EPA is not proposing this option because we are concerned about the economic impacts of a mandatory third-party certification requirement on manufacturers with fewer than 100 employees. Some of these manufacturers likely produce or fabricate small quantities of products that may be custom-made for a single specific use with a customer. A requirement for third party certification in these instances may be impractical and costly per unit produced. For those reasons, EPA chose the approach described in this proposal.

EPA also considered the option of allowing all manufacturers the option of electing third party certification or self-certification for their various products. This option would allow maximum flexibility for manufacturers and would likely limit financial impacts to firms that currently do not get their products independently certified. EPA opted not to propose this approach because we found that (currently) the most widely used model plumbing codes require many products to be third party certified, and that there already exists a high level of adoption of third party standards in the plumbing industry. Additionally, requiring all but the smallest firms to certify their products using third party certification bodies would ensure that the vast majority of products sold in the marketplace are independently verified as lead free.

EPA solicits comments on this aspect of the proposed rule, including EPA's rationale as described in this preamble. In addition, EPA specifically solicits comments, information and data on the following topics:

1. Should third party certification be required of U.S. manufacturers regardless of the number of employees?

2. Should U.S. manufacturers have the option of conducting either third party certification or self-certification for products they produce?

3. Is there a need for some manufacturers to have a self-certification option?

4. Should third party certification be required of importers of foreign manufactured plumbing materials regardless of the number of employees at the foreign manufacturer?

5. Is there a more appropriate break point (e.g., fewer than 20 employees, fewer than 500 employees based on other categories of Census Bureau's Statistics of U.S. Businesses) for allowing self-certification?

6. Conversely, should all importers of foreign manufactured plumbing products be eligible for self-certification?

7. Is the definition of importer in § 143.11 of this proposed rule adequate to ensure compliance with the proposed requirements?

8. Are there more appropriate criteria for requiring third party certification for manufacturers based on classes of products that EPA should evaluate, such as more complicated multi-component devices (for example, valves, faucets, pumps, water coolers, etc.), but allowing an option of self-certification for simple single component plumbing pieces (for example, elbow joint, gasket, pipe, etc.); or alternatively, based on whether a product is mass produced or custom fabricated?

9. Should self-certification be allowed for all products made by any manufacturer if the product is composed of a single material such as pure copper?

10. For self-certification, is the requirement for a "certificate of conformity" and its proposed content appropriate, or should there be another process for self-certification or is there other content for the "certificate of conformity" that would be more appropriate?

11. Should any product certification be required?

#### *E. Other Regulatory Requirements and Clarifications*

##### 1. Compliance Information Authority

In order to effectively enforce the lead free requirements of the SDWA and the proposed implementing regulations, EPA needs the ability to obtain, if necessary on a case-by-case basis, certain compliance related information from manufacturers, importers,

wholesalers and retailers and others subject to SDWA section 1417, such as information related to the calculation of the weighted average of wetted surfaces, schematics of fittings/fixtures, certification documentation, purchases/sales dates, and examples of lead free product and/or package messaging. This proposed rule contains a provision providing the EPA Administrator with explicit authority to request such information on a case-by-case basis and a requirement for entities to provide the information requested to the Administrator. This provision is based on statutory authority contained in section 1445 of the SDWA.

##### 2. State Enforcement of Use Prohibitions

EPA is proposing language in § 143.14 to codify in regulation that the SDWA 1417(b) requirement for states to enforce the use prohibition on pipe, pipe fittings or fixtures, any solder, or any flux that are not lead free is a condition of receiving a full Public Water System Supervision grant allocation. Under SDWA 1417(b)(1), the state enforcement provision only applies to the use prohibition in section 1417(a)(1); it does not apply to the introduction into commerce prohibition in section 1417(a)(3) of the SDWA, nor would it apply to the proposed requirements for labeling and certification.

#### *F. Implementation*

The revised definition of lead free has been in effect since January 4, 2014, as per the RLDWA and the CFSA. EPA is proposing that labeling and the product certification requirements contained within this proposal will be in effect three years from the date the final regulation is published, consistent with the three-year time period provided under the RLDWA and CFSA. EPA is also proposing that all other provisions are effective 30 days after the date the final regulation is published, because those provisions merely codify statutory provisions already in effect.

EPA solicits comments on all aspects of the proposed implementation period for this proposed rule. EPA specifically requests comments, information and data on whether three years is an appropriate timeframe to achieve compliance with the proposed labeling and certification requirements, or is a different timeframe more appropriate? Is there a need for a different effective date for any other provisions of the rule?

#### **V. Costs**

EPA collected data from public sources and private data vendors to develop the estimated rule costs to plumbing manufacturing firms. Annual

production of potable use products and products eligible for the “used exclusively” exemption is 1.3 billion units and 500 million units, respectively. There are 2,193 firms producing plumbing products impacted by this proposed rule, which are spread

across 14 NAICS codes. Table V.1 summarizes information for the segment of the industry that produces potable use products. Table V.2 summarizes the data for the segment of the industry that produces products eligible for the “used exclusively” exemption. Both tables

break production into product subcategories and provide EPA’s estimated annual production values, the NAICS code assigned and the number of manufacturers in the subcategory.

TABLE V.1—PRODUCT SUBCATEGORIES, PRODUCTION, NAICS AND NUMBER OF MANUFACTURERS EPA IDENTIFIED FOR POTABLE USE PRODUCTS

Product category	Product name	Units produced annually (2013)	NAICS for product	Number of manufacturers for product
Pipe and Fittings .....	Copper Tube (<4” in diameter) .....	233,049,645	332996	213
	PEX Pipe (<4” in diameter) .....	348,583,587	326122	27
	CPVC Pipe (<4” in diameter) .....	148,219,048	326122	48
	Copper Fittings (<4” in diameter) .....	93,219,858	332913	119
	Brass Fittings (<4” in diameter) .....	80,026,241	332913	523
	PEX Fittings (<4” in diameter) .....	99,620,061	332913	47
	CPVC Pipe Fittings (<4” in diameter) .....	59,287,619	332913	63
	Small and Mid-Diameter PVC Pipe .....	58,257,345	326122	143
	PVC Pipe Fittings .....	14,927,862	332913	103
	Faucets and Mixers .....	Kitchen and Bar Faucet Market .....	8,531,915	332913
Lavatory Faucet .....		18,635,258	332913	74
Kitchen Sinks and Accessories.	Kitchen Sink .....	4,730,496	332999	24
	Sink Strainer .....	11,036,332	332999	24
Residential Water Filtration Products.	Point-of-entry Residential Water Filtration Market .....	1,236,699	333318	713
	Point-of-use Counter Top Water Filtration Market .....	72,857	333318	694
	Point-of-use Under the Sink Water Filtration Market .....	261,702	333318	704
	Point-of-use Faucet Mount Water Filtration Market .....	1,707,194	333318	694
Stop Valves, Stainless Steel Braided Hoses, Inline Valves.	Stop Valve Market .....	9,455,319	332911	23
	Stainless Steel Braided Hose Market .....	9,424,559	333999	204
Water Heaters and Boilers	Residential Inline Valve Market .....	30,597,771	332919	204
	Combi Boiler Market .....	55,527	333999	15
	Residential Gas Tankless Water Heater Market .....	410,831	335228	20
	Residential Gas Storage Water Heaters .....	4,338,506	335228	11
	Residential Electric Storage Water Heaters .....	4,061,277	335228	11
	Residential Indirect Fired Water Heater Market .....	133,647	335228	10
	Residential Electric Tankless Water Heater Market .....	276,398	335228	19
	Residential Solar Storage Water Heater Market .....	21,819	335228	42
	Residential Oil Water Heaters .....	31,692	335228	1
	Commercial Gas Storage Water Heater Market .....	89,706	335228	11
Water Coolers/Drinking Fountains/Bubblers.	Commercial Electric Storage Water Heater Market .....	70,071	335228	15
	Water Cooler/Drinking Fountain/Bubbler Market .....	557,244	333415	5
Household Appliances .....	Refrigerators with Water Dispenser/Ice Making Machinery.	4,540,527	335222	7
	Dishwasher Market .....	5,537,416	335228	5
	Water Softener Market .....	3,444,782	333318	98
Household & Commercial Appliances.	Coffee Makers .....	234,247	333318	40
	Other .....	Aerator .....	27,167,173	332913
Backflow preventers/Vacuum Breakers .....		32,202	332913	11
Gaskets/O-rings .....		5,433,435	339991	13
Pumps .....		1,808,369	333911	19
Water Meters/End Point Meters .....		7,053,100	334514	68

Source: Technical Support Document, Exhibits 3–3 and 3–11 (USEPA, 2016).

TABLE V.2—PRODUCT SUBCATEGORIES, PRODUCTION, NAICS AND NUMBER OF MANUFACTURERS EPA IDENTIFIED FOR PRODUCTS ELIGIBLE FOR THE “USED EXCLUSIVELY” EXEMPTION

Product category	Product name	Units produced annually (2013)	NAICS for product	Number of manufacturers for product
Pipe and Fittings .....	Copper Tube (<4” in diameter) .....	81,033,435	332996	213
Pipe and Fittings Faucets and Mixers.	PEX Pipe (<4” in diameter) .....	59,116,515	326122	27

TABLE V.2—PRODUCT SUBCATEGORIES, PRODUCTION, NAICS AND NUMBER OF MANUFACTURERS EPA IDENTIFIED FOR PRODUCTS ELIGIBLE FOR THE “USED EXCLUSIVELY” EXEMPTION—Continued

Product category	Product name	Units produced annually (2013)	NAICS for product	Number of manufacturers for product
Stop Valves, Stainless Steel Braided Hoses, Inline Valves.	CPVC Pipe (<4” in diameter) .....	39,876,190	326122	48
	Copper Fittings (<4” in diameter) .....	32,413,374	332913	119
	Brass Fittings (<4” in diameter) .....	27,825,836	332913	523
	PEX Fittings (<4” in diameter) .....	16,894,630	332913	47
	CPVC Pipe Fittings (<4” in diameter) .....	15,950,476	332913	63
	Small and Mid-Diameter PVC Pipe .....	68,389,058	326122	143
	PVC Pipe Fittings .....	35,048,024	332913	103
	Laundry Faucet .....	1,122,594	332913	72
	Stop Valve Market .....	62,175,887	332911	23
	Stop Valves, Stainless Steel Braided Hoses, Inline Valves, Other.	Stainless Steel Braided Hose Market .....	106,928,024	333999
Aerator .....		1,122,594	332913	3
Other .....	Backflow preventers/Vacuum Breakers .....	79,265	332913	11
	Gaskets/O-rings .....	224,519	339991	13
	Pumps .....	21,914	333911	19

Source: Technical Support Document, Exhibits 3–6 and 3–12 (USEPA, 2016).

EPA developed cost estimates for this proposed rule along with two additional regulatory alternatives EPA considered in the development of the proposal. All three regulatory options contain estimates for initial administrative and

implementation costs, costs to modify their product and/or package messaging, third party or self-certification costs, and response to data request costs. The three options are presented in Table V.3. Option B is the regulatory option

selected for this proposal. The Technical Support Document (USEPA, 2016) provides more detailed information on the costing methodology and a discussion of the uncertainties and limitations of this assessment.

TABLE V.3—REGULATORY OPTIONS

Option	Option description
A .....	<ul style="list-style-type: none"> <li>• Product labels and package marking for potable use products.</li> <li>• Third party certification required for all firms.</li> </ul>
B .....	<ul style="list-style-type: none"> <li>• Product labels and package marking for potable use products.</li> <li>• Self-certification or third party certification for &lt;100 Employees; Third party certification only for ≥100 Employees.</li> </ul>
C .....	<ul style="list-style-type: none"> <li>• Product labels or package marking for potable use products.</li> <li>• Third party certification or self-certification for all firms.</li> </ul>

*A. Initial Administrative and Initial Implementation Costs*

The analysis for initial administrative and implementation costs was conducted at the level of the manufacturing firm. These costs do not vary by regulatory option. EPA estimated that it would take each firm an average of 8 hours to read and understand the rule once promulgated. This time estimate when multiplied by an average labor rate of \$71.72 and the number of firms affected by the rule, 2,193, gives a total cost of \$1.26 million.

EPA also estimated the cost to manufacturing firms that would have to redesign their product and/or package messaging to include lead-related information. To calculate the cost of package and product messaging redesign, EPA first estimated the total number of product types across 46 product subcategories. A total of 5,705 product types were identified. EPA estimated a percent range of firms that would be required to redesign their product and package in order to comply with this proposed rule. Firms with greater than 500 employees are estimated to redesign 10 percent of

product and package messaging. Manufacturers with fewer than 500 employees are assumed to redesign between 25 and 50 percent of their product and package messaging. Redesign was estimated to require 5 hours of labor multiplied by the number of products, giving a total costs range between \$0.24 and \$0.47 million.

Table V.4 summarizes, by size category, the initial rule implementation annualized cost ranges. The values were discounted at both the 3 and 7 percent rates over the 25-year period of analysis. Annual total initial implementation costs range from \$0.08 to \$0.14 million.

TABLE V.4—RULE INITIAL ADMINISTRATIVE AND INITIAL IMPLEMENTATION ANNUALIZED COSTS, IN MILLIONS [2014\$]

Manufacturer size (no. of employees)	Read and understand the rule		Messaging design change		Initial rule implementation cost	
	Discount rate		Discount rate		Discount rate	
	3%	7%	3%	7%	3%	7%
<100 .....	\$0.051	\$0.073	\$0.011–0.021	\$0.015–0.03	\$0.061–0.072	\$0.088–0.103
100–499 .....	0.001	0.016	0.002–0.005	0.003–0.007	0.014–0.016	0.020–0.023
≥500 .....	0.008	0.012	0.001–0.001	0.001–0.001	0.009–0.009	0.013–0.013
All Sizes .....	0.07	0.101	0.014–0.027	0.02–0.038	0.084–0.097	0.121–0.139

Source: Technical Support Document, Exhibits 4–7a and 4–7b (USEPA, 2016).

*B. Labeling Potable Use Products*

In order to estimate the potential cost of this proposed rule and the two alternative regulatory scenarios presented in this proposed rule preamble, EPA collected information on current labeling practices to set the regulatory baseline. EPA developed three baseline scenarios characterizing the proportion of firms by size category that either currently have lead free labeling (meeting the requirements of this proposed rule), have product messaging not related to lead free requirements, or have no product messaging. These three scenarios capture the uncertainty surrounding

EPA’s understanding of current industry labeling practices. Table V.5 presents preexisting labeling assumptions that represent the lower bound for regulatory cost estimates. Table V.6 shows a possible lower level baseline of product labeling. This table represents the upper bound for rule cost estimate. Across both lower and upper bound scenarios, EPA has made the conservative assumption that 5 percent of all firms have no messaging on product or package. Also common across the scenarios, is the concept that firms with greater numbers of employees have larger production totals and serve larger market areas and, therefore, will have a

higher probability of selling in markets that already require lead content labeling on product and package. The upper bound scenario assumes manufacturers with fewer than 500 employees mark products with lead content messaging 50 percent of the time, while in the lower bound scenario, those same firms label 75 percent of products with lead content messaging. Also, firms in the upper bound scenario with less than 100 employees mark 50 percent of their packaging with lead content labeling. The lower bound assumes that firms with fewer than 100 employees label 75 percent of packaging with lead content information.

TABLE V.5—ESTIMATED PERCENTAGE OF POTABLE USE PRODUCTS WITH AND WITHOUT EXISTING MESSAGING [Lower bound]

Manufacturer size (number of employees)	Percent with lead-content messaging		Percent with existing messaging but not lead-related (incur partial messaging costs)		Percent with no messaging (incur total messaging costs)	
	Product	Package	Product	Package	Product	Package
<100 .....	75	75	20	20	5	5
100–499 .....	75	90	20	5	5	5
≥500 .....	90	90	5	5	5	5

Source: Technical Support Document, Exhibit 4–8a (USEPA, 2016).

TABLE V.6—ESTIMATED PERCENTAGE OF POTABLE USE PRODUCTS WITH AND WITHOUT EXISTING MESSAGING [Upper bound]

Manufacturer size (number of employees)	Percent with lead-content messaging		Percent with existing messaging but not lead-related (incur partial messaging costs)		Percent with no messaging (incur total messaging costs)	
	Product	Package	Product	Package	Product	Package
<100 .....	50	50	45	45	5	5
100–499 .....	50	90	45	5	5	5
≥500 .....	90	90	5	5	5	5

Source: Technical Support Document, Exhibit 4–8b (USEPA, 2016).

Using the assumptions on current industry messaging practices detailed in Tables V.5 and V.6, EPA applied its unit compliance technology costs for both product and package labeling in the following way: (1) Firms that currently have lead content messaging on both

product and package are assumed to have no labeling costs in this regulatory analysis; (2) manufacturers that currently mark their product and/or package with some messaging (e.g., company name and marketing materials, a description of how the product is

used, installation instructions or other certification and identification information) were assigned a partial cost to implement the requirements of this proposed rule; and (3) firms assumed to have no product labeling on package or product received full capital and O&M

costs as part of the regulatory assessment of costs.

Under regulatory options requiring lead free marking on potable use products, EPA assigned to each of the 40 identified product subcategories one of three compliance technologies: Printing on product (e.g., copper or plastic pipe), modification of production molds and patterns through the use of electric diode machining (e.g., brass fittings), or attaching a tag with wire or another non adhesive method (e.g., water heaters).<sup>1</sup>

For regulatory costing scenarios that required lead free labeling on product packages, EPA (again) assigned one of

three compliance technologies to each of the 40 potable use product categories. The compliance technologies are printing on product box (e.g., faucets), printing on product bag (e.g., copper and brass fittings), or adhesive label (e.g., braided steel hose).<sup>2</sup>

Unit capital and O&M costs for each of the six compliance technologies were derived with information collected from both the PMI and AFS trade associations and information from tool and die firms, product packaging vendors, and printing equipment suppliers.

Table V.7 provides EPA's estimated total annual cost ranges for potable use

product lead free messaging on product and/or package for the three options considered as part of the regulatory analysis. For Options A and B, costs include labeling on both the product and package and range from \$8.69 to \$13.60 million (2014\$) dollars annually. For Option C, which gives producers the choice to label the product or package, EPA assumed that impacted firms would choose the lower cost package labeling alternative; therefore, annual costs range from \$1.14 to \$1.28 million dollars.

TABLE V.7—TOTAL ANNUALIZED PRESENT VALUE COSTS FOR LEAD FREE LABELING OF POTABLE USE PRODUCTS ON PRODUCT AND PACKAGE, MILLIONS [2014\$]

Option	3% Discount rate in millions (2014\$)	7% Discount rate in millions (2014\$)
A: Product and package messaging .....	\$8.69–10.34	\$11.32–13.60
B: Product and package messaging .....	8.69–10.34	11.32–13.60
C: Product or package messaging .....	1.17–1.28	1.14–1.26

Source: Technical Support Document, Exhibits 4–13a and 4–13b (USEPA, 2016).

C. Labeling of Products Eligible for the “Used Exclusively” Exemption

As discussed in section IV.C, EPA has included an additional means of qualifying for the “used exclusively” exemption.

The proposed provision to label products to establish that the products are “used exclusively” in nonpotable services provides a less costly option to persons introducing the product into commerce. If the proposed regulations limited the availability of the “used exclusively” exemption to products that are physically incompatible with potable water systems, then persons introducing non-potable water plumbing products into commerce that are physically compatible and capable of being connected to systems providing

water for human consumption would be required to assure that these products meet the lead free requirements. Alternatively, they could or redesign their products to make them physical incompatible with potable water systems. EPA anticipates that the costs associated with designing and applying a label are likely to be less than the costs associated with reformulating the alloy and overhauling the manufacturing processes associated with meeting the “lead free” requirements. Therefore, this optional compliance alternative will not result in increased costs or burden, and will result in a cost savings for those manufacturers who elect to take advantage of this proposed optional exemption mechanism.

There are six product subcategories that are both physically compatible with

potable use applications and would meet the lead content limit of 0.25 percent of wetted surfaces to be considered lead free. In order to develop costs for this requirement EPA first determined the baseline current industry practices when it comes to labeling products eligible for the “used exclusively” exemption and their packaging. Table V.8 shows the lower bound percentage of products by firm size category that currently use lead content messaging, messaging of some kind (e.g., marks, serial numbers, installation instructions), and have no labeling on product or packaging. Table V.9 details the upper bound baseline assumed percentages for labeling by firm size for products eligible for the “used exclusively” exemption.

TABLE V.8—ESTIMATED PERCENTAGE OF PRODUCTS ELIGIBLE FOR “USED EXCLUSIVELY” EXEMPTION WITH AND WITHOUT EXISTING MESSAGING [Lower bound]

Manufacturer size (number of employees)	Percent with lead-related messaging		Percent with existing messaging but not lead-related (incur partial messaging costs)		Percent with no messaging (incur total messaging costs)	
	Product (%)	Package (%)	Product (%)	Package (%)	Product (%)	Package (%)
<100 .....	50	50	45	45	5	5
100–499 .....	75	75	20	20	5	5

<sup>1</sup> Small products like gaskets and o-rings are assumed to be bagged with lead free messaging.

<sup>2</sup> Products that are not sold with packaging like pipe are assumed to comply by printing on product.

TABLE V.8—ESTIMATED PERCENTAGE OF PRODUCTS ELIGIBLE FOR “USED EXCLUSIVELY” EXEMPTION WITH AND WITHOUT EXISTING MESSAGING—Continued  
[Lower bound]

Manufacturer size (number of employees)	Percent with lead-related messaging		Percent with existing messaging but not lead-related (incur partial messaging costs)		Percent with no messaging (incur total messaging costs)	
	Product (%)	Package (%)	Product (%)	Package (%)	Product (%)	Package (%)
≥500 .....	75	75	20	20	5	5

Source: Technical Support Document, Exhibit 4–14a (USEPA, 2016).

TABLE V.9—ESTIMATED PERCENTAGE OF PRODUCTS ELIGIBLE FOR “USED EXCLUSIVELY” EXEMPTION WITH AND WITHOUT EXISTING MESSAGING  
[Upper bound]

Manufacturer size (number of employees)	Percent with lead-related messaging		Percent with existing messaging but not lead-related (incur partial messaging costs)		Percent with no messaging (incur total messaging costs)	
	Product (%)	Package (%)	Product (%)	Package (%)	Product (%)	Package (%)
<100 .....	25	25	70	70	5	5
100–499 .....	50	50	45	45	5	5
≥500 .....	50	50	45	45	5	5

Source: Technical Support Document, Exhibit 4–14b (USEPA, 2016).

EPA assumed manufacturers of products eligible for the “used exclusively” exemption that currently do not have lead-related information on their product would use the same compliance technologies that would be used for the labeling of potable use products and packages. For labeling on the product, EPA assigned each of the subcategories as either the printing on product or the mold modification

compliance technology.<sup>3</sup> Also, for package compliance, EPA assigned the print on bag compliance technology. Under the “used exclusively” exempt package marking requirements, piping products are required to be printed directly on the product since they are generally not packaged.

EPA used the same unit cost information that was developed for the potable use labeling requirements. Table

V.10 details, by size category, the regulatory annual total cost ranges for labeling those products eligible for the “used exclusively” exemption not for potable use applications. This cost component does not vary by regulatory option. Annual total cost for labeling products that are not for potable use range from \$0.14 to \$0.22 million.

EXHIBIT V.10—TOTAL ANNUALIZED PRESENT VALUE COSTS FOR LEAD-RELATED MESSAGING ON PRODUCTS ELIGIBLE FOR THE “USED EXCLUSIVELY” EXEMPTION ON PACKAGE OR PRODUCT, MILLIONS  
[2014\$]

Manufacturer size (number of employees)	3% Discount rate in millions (2014\$)	7% Discount rate in millions (2014\$)
<100 .....	\$0.03–\$0.03	\$0.02–\$0.03
100–499 .....	0.01–0.01	0.01–0.01
≥500 .....	0.11–0.17	0.10–0.16
Total Cost .....	0.15–0.22	0.14–0.20

Source: Technical Support Document, Exhibit 4–17 (USEPA, 2016), Rule Component All Sizes worksheet.

D. Product Certification

In order to develop total compliance costs for third party certification, EPA had to determine the regulatory baseline. This baseline represents the current industry practice with regard to third party certification. EPA collected information on use of third party

certification by plumbing manufacturers by reviewing current state laws requiring certification for NSF Standard 61 and 372; reviewing the International and Uniform Plumbing Codes; contacting the two primary industry trade groups, PMI and AFS; and acquiring information from industry third party certifiers (e.g., NSF

International, CSA Group, UL, etc.). Based on the collected information, EPA assumed that 90 percent of manufacturers with 100 or greater employees already use an accredited third party agency to certify that their products are lead free. As with potable use product labeling, third party certification costs are a major driver of

<sup>3</sup> Small products like gaskets and o-rings are assumed to be bagged with lead free messaging.

overall cost to manufacturers; therefore, EPA chose to develop lower and upper bound cost scenarios based on baseline compliance assumptions for firms having less than 100 employees. Fifty to 75 percent of plumbing manufacturers

having fewer than 100 employees are assumed to use third party certifiers. Table V.11 summarizes the third party certification baseline assumptions EPA used in the development of regulatory costs. Under all regulatory options,

certification costs would only be attributable to those manufacturers that do not already use these third party certification bodies.

TABLE V.11—ESTIMATED PERCENTAGE OF MANUFACTURERS THAT DO NOT ALREADY USE THIRD PARTY CERTIFICATION BODIES

Manufacturer size (number of employees)	Percentage of manufacturers that currently do not use third party certifying bodies and to which certification costs would apply	
	Lower bound (%)	Upper bound (%)
<100 .....	25	50
100–499 .....	10	10
≥500 .....	10	10

Source: Technical Support Document, Exhibit 4–18 (USEPA, 2016).

Third party certifying firms usually conduct the certification process according to product families. For NSF/ANSI Standard 372, products of the same material formulation and similar configuration are considered one product family. Thus, certifying costs were developed on a product family basis. EPA estimated that each firm produces an average of three product families, based on an assessment of firm Web site data for manufacturers across all potable use product subcategories.

Certification costs can be broken into initial assessment and testing costs and annual renewal costs. Most of the accredited third party certification bodies offer an annual renewal based on an audit process for a set number of years after the initial certification year. In order to derive initial and renewal certification unit costs, EPA contacted the eight ANSI accredited third party certification bodies to obtain estimated costs for certifying products to ANSI/NSF Standard 372. The certifiers were asked to provide estimates for four representative product categories (faucets, fittings, valves and pipes), which are intended to represent the range in complexity of plumbing products.

Four certification bodies provided quotes of sufficient specificity or comparable scope to be used in estimating initial certification costs. None of the firms provided quotes for

all four product lines. Costs varied based on the product type and certifying body. EPA used the average of these quotes across firms and product types to derive a composite estimated cost of \$6,000 for an initial certification of a single product family. Five of the eight certification bodies provided estimates for annually renewing the third party certification to Standard 372. Costs varied based on the product type and certification body. One of the responding certifiers requires re-certification annually. The other four certification bodies require renewal on a less frequent basis, the longest being every five years. EPA determined a five-year cost stream for each of the third party certifiers and computed a per product family average annual renewal cost of \$3,200. In addition to the certifiers' fees, EPA assumed a \$224 annualized cost for recordkeeping on the part of the plumbing manufacturing firms.

Both the preferred proposed rule Option B and Option C allow for some firms to self-certify compliance with lead free requirements. EPA estimated that each manufacturer would require 40 hours of labor to initially develop the certificate of conformity (the requirement of the certificate of conformity can be found in section IV.D of this preamble) which certifies a product family as being compliant with the lead free requirements. The unit cost

per product family is \$1,122. The labor burden for the annual renewal of the self-certification per product family is estimated to be 16 hours. These hours are used to update the certificate of conformity and perform recordkeeping activities. This means the unit cost of annual self-recertification is \$449 per product family.

Table V.12 provides EPA's estimated total annual cost ranges for potable use product certification requirements of this proposed rule and other options that were considered. Unit certification costs were multiplied by the number of firms and average number of product families. Option A's cost range of \$11.20 to \$21.58 million reflects a third party certification requirement for all regulated firms. Option B, the proposed option, requires third party certification for firms with 100 or more employees and gives the option of self-certification to firms with fewer than 100 employees. Annual costs for Option B range from \$2.82 to \$4.31 million. The analysis of Option C assumes that all firms, when given the less costly self-certification choice, will opt for that compliance path. Therefore, the annual costs that range from \$1.52 to \$2.98 million reported here are for all firms conducting self-certifications. EPA did not assess any cost savings to firms that would no longer choose to have products third party certified.



TABLE V.12—TOTAL ANNUALIZED PRESENT VALUE COSTS FOR DEMONSTRATION OF COMPLIANCE REQUIREMENTS, MILLIONS [2014\$]

Option	3% Discount rate in millions (2014\$)	7% Discount rate in millions (2014\$)
A: Third party certification only .....	\$11.20–\$20.90	\$11.56–\$21.58
B: Third party for ≥100; Choice of self-certification for <100 (Proposed Rule) .....	2.82–4.14	2.93–4.31
C: Third party certification or self-certification .....	1.52–2.84	1.59–2.98

Source: Technical Support Document, Exhibits 4–23a and 4–23b (USEPA, 2016).

Note: Under Option C, all manufacturers are assumed to select the less costly choice of self-certification.

E. Response to EPA Data Request Costs

Under all three of the proposed regulatory options, plumbing manufacturers will be required to respond to EPA’s requests for product information (See section IV.E.1.a for a detailed description of the data request provision). EPA assumed that firms would spend an average of 20 hours responding to each data request, resulting in a unit cost of \$1,434. As

part of the cost assessment, EPA multiplied the per unit cost by 10 unique data requests per year, starting in the fourth year after promulgation of the final rule and continuing over the 25-year period of analysis. Seventy percent of requests would be to firms with 500 or more employees, 20 percent of requests would be to firms with 100 to 499 employees, and firms with fewer than 100 employees would receive the

remaining 10 percent. This breakdown of requests between firm size categories roughly corresponds to the proportion of total products produced by firms in each of the size categories. Table V.13 shows the total annualized cost of EPA data request response by firm size category. Total data request costs range from approximately \$12,400 a year discounted at 3 percent to about \$11,900 a year when discounted at 7 percent.

TABLE V.13—TOTAL ANNUALIZED PRESENT VALUE COSTS FOR RESPONDING TO DATA REQUESTS, IN MILLIONS [2014\$]

Manufacturer size (number of employees)	3% Discount rate	7% Discount rate
<100 .....	\$0.0012	\$0.0012
100–499 .....	0.0025	0.0024
≥500 .....	0.0087	0.0083
All Sizes .....	0.0124	0.0119

Source: Technical Support Document, Exhibit 4–25 (USEPA, 2016).

VI. Economic Impacts Analysis

EPA assessed the social costs and the projected economic impacts of the three regulatory options described in this proposal. This section provides an overview of the methodology EPA used to assess the social costs and the economic impacts of this proposed rule and summarizes the results of these analyses. The Technical Support Document (USEPA, 2016), which is available in the docket, provides more details on these analyses, including discussions of uncertainties and limitations.

A. Annualized Social Costs Estimates

EPA estimated the total annualized social costs to plumbing manufacturers by summing the rule’s component costs,

which include administrative requirement costs, the cost to potable use product manufacturers for both labeling on the product and on the product’s packaging, the cost to manufacturers of products eligible for the “used exclusively” exemption for package labeling indicating non-compliance with lead free requirements, third party- and self-certification costs, and the costs of responding to EPA data requests. EPA annualized the stream of future costs using both the 3 percent (the social discount rate) and 7 percent (opportunity cost of capital) discount rates. EPA annualized one-time costs over the period of analysis, 25 years. Capital and O&M costs recurring on other than an annual basis were annualized over a specific useful life,

implementation, and/or event recurrence period (i.e., 10 years for mold modifications), using rates of 3 and 7 percent. EPA added the annualized capital, initial one-time costs, and the non-annual portion of O&M costs to annual O&M costs to derive total annualized compliance costs, where all costs are expressed on an equivalent constantly recurring annual cost basis.

Table VI.1 presents the total annualized compliance costs of the regulatory options. As shown in the table, total annualized compliance costs range between \$3 million and \$36 million for Options C and A, respectively, with the proposed option (Option B) estimated to have annualized costs of \$12 million to \$18 million.

TABLE VI.1—TOTAL ANNUALIZED SOCIAL COSTS [Millions, 2014\$]

Regulatory option <sup>1</sup>	3% Discount rate	7% Discount rate
A: Label product and packaging/third party certification .....	\$20.1–\$31.6	\$23.1–\$35.5
B: (Proposed Rule): Label product and packaging/third party certification for manufacturers ≥100 employees and third party or self-certification for others .....	11.8–14.8	14.5–18.3

TABLE VI.1—TOTAL ANNUALIZED SOCIAL COSTS—Continued  
[Millions, 2014\$]

Regulatory option <sup>1</sup>	3% Discount rate	7% Discount rate
C: Label product or packaging/third party or self-certification .....	2.9–4.5	3.0–4.6

Source: Technical Support Document, Exhibit 4–27 (USEPA, 2016).

<sup>1</sup> Table includes annualized costs for rule implementation, certification of potable use products, lead-related messaging for potable use products and products eligible for the “used exclusively” exemption, and EPA requests for data.

### B. Economic Impacts—Cost-to-Revenue Analysis

To provide an assessment of the impact of the rule on plumbing manufacturing firms, EPA used a cost-to-revenue analysis. The cost-to-revenue analysis compares the total annualized compliance cost of each regulatory option with the revenue of the impacted entities. This same analysis is also used under the Regulatory Flexibility Act (RFA) to determine if a rule has the potential to have a significant impact on a substantial number of small entities.

In order to conduct the cost-to-revenue test, EPA developed a list of 2,193 manufacturers that participate in the production of specific types of plumbing products for both potable use and those eligible for the “used exclusively” exemption. These firms were assigned to a NAICS code, based on the type of plumbing product they manufacture. Firm size distributional information, based on number of employees, available from the U.S. Census Bureau’s Statistics of U.S. Businesses for the year 2012 was then used to parse the number of entities in each NAICS code into a number of small business and large firm categories. In this way, the number of firms in each of the 14 NAICS codes having seven employee size categories each (e.g., 0–4, 5–9, 10–19, 20–99, 100–499, 500+ to the Small Business Administration (SBA) small business threshold, and large firms above the SBA threshold) was derived. Computation of total average firm cost under each of the NAICS/employee entity size categories was developed by applying the estimated unit fixed and variable costs to each regulatory option. In order to calculate

total average variable costs for each size category, unit variable costs must be adjusted by the units produced and firms producing in each of the NAICS/employee size categories. To determine the number of units produced per NAICS/employee size category, EPA used information from the U.S. Census Bureau’s Statistics of U.S. Businesses. The Census Bureau does not provide units produced for each of the NAICS employee size categories, so EPA used the percent of firm receipts by size category as a proxy. The approximated units per size category were then divided by the estimated number of entities in the category (derivation of the number of entities per NAICS/employee size category was previously described) giving average units produced per firm. Average units per firm for each size category was multiplied by unit variable cost to get total variable cost for each NAICS/employees size category. The Census does not provide revenue values by NAICS and employee sizes, so EPA used data on total annual receipts (assuming receipts is an unbiased estimator) by NAICS/employee size categories as a close (although more conservative) approximation of revenue. The total receipts information was divided by the number of firms per category to approximate average revenue.

EPA then compared the computed average annual costs to the average revenue for each of the NAICS/employee size categories. If average cost exceeded revenue by 1 percent, all firms assigned to that category were assumed to incur impacts. Likewise, if average annual cost exceeded revenue by 3 percent in a NAICS/employee size category, all entities in that category are

assumed to be impacted at the 3 percent level. Impacted firms are summed across NAICS codes and employee size categories to assess the total impact to the industry.

Table VI.2 summarizes the cost-to-revenue analysis results for the three main regulatory options. The table only shows the largest impact scenarios analyzed, based on upper bound compliance cost estimates, and using a 7 percent discount rate. For the lower bound cost and 3 percent discounted impact results see the Technical Support Document (USEPA, 2016). Under Option B, which represents this proposed rule (which includes costs for rule implementation, potable use labeling costs for both package and product, labeling of products eligible for the “used exclusively” exemption that do not meet lead free requirements, third party certification cost for firms with 100 or more employees and third party or self-certification costs for firm with fewer than 100 employees, and data request costs), EPA estimates that the vast majority of plumbing manufacturing firms subject to the regulations will incur annualized costs amounting to less than 1 percent of revenue (2163 firms, or 98.6 percent of the total 2,193 manufacturers). A total of 29 firms (2 percent of small firms) had impacts between 1 and 3 percent of revenue, and no small manufacturers had impacts above 3 percent, given the costs estimated for Option B. The analysis of Option B also found that 1 large entity (0.5 percent of large firms) had impacts between 1 and 3 percent of revenue, and no large firms were impacted at the 3 percent revenue threshold.

TABLE VI.2—SUMMARY OF COST-TO-REVENUE ECONOMIC IMPACT ANALYSIS  
 [Upper bound scenario, small entities 7% discount rate, large entities 3% discount rate]

Option	Option description <sup>1</sup>	Small entities (7% discount rate)					Large entities (3% discount rate)				
		Count <sup>2</sup>			Percentage		Count <sup>2</sup>			Percentage	
		Total	≥1%	≥3%	≥1%	≥3%	Total	≥1%	≥3%	≥1%	≥3%
A .....	Product and Package Costs for Potable Product or Package Costs for “Used Exclusively” Exempt Product, 3rd Party Cert for all manufacturers.	1,976	783	27	40	1	217	1	0	0.5	0.0
B .....	Product and Package Costs for Potable Product or Package Costs for “Used Exclusively” Exempt Product, 3rd Party Cert for ≥100 employees, Self or 3rd Party Cert for <100 employees.	1,976	29	0	2	0	217	1	0	0.5	0.0
C .....	Product or Package Costs for Potable Product or Package Costs for “Used Exclusively” Exempt Product, Self or 3rd Party Cert for all manufacturers.	1,976	0	0	0.0	0.0	217	0	0	0.0	0.0

Source: Technical Support Document, Exhibit 6–7 (USEPA, 2016).

<sup>1</sup> All options also include implementation and data request costs. For Option B, EPA assumes that manufacturers <100 employees choose the least cost option of self-certification. For Option C, EPA assumes all manufacturers pick the least cost option of self-certification. In addition, for Option C, EPA assumes manufacturers choose the least cost option for labeling, which is usually package labeling except when the products do not have packaging.

<sup>2</sup> Counts of impacted entities are rounded up to 1 if they fall between 0 and 1.

EPA solicits comments on the economic analysis for this proposed rule, including EPA’s cost analysis and benefits assessment as described in this preamble and the Technical Support Document (USEPA, 2016) for this proposed rule. Comments are most helpful when accompanied by specific examples or supporting data.

**VII. Benefits**

EPA did not quantify the expected change in health endpoints for this proposed regulation. EPA assessed the health effects associated with reductions in lead ingestion qualitatively using two main sources: (1) The EPA “Integrated Science Assessment for Lead” (USEPA, 2013b); and (2) the National Toxicity Program’s Monograph on Health Effects of Low-level Lead (USHHS, 2012).

A wealth of information exists on the adverse health effects associated with lead exposure. When ingested, lead is distributed throughout the body and can affect many organ systems. Lead is a highly toxic contaminant that can cause adverse neurological, cardiovascular, renal, reproductive, developmental, immunological and carcinogenic effects. The neurological effects are particularly pronounced in children; however, recent studies in the public health literature have found that a wide spectrum of adverse health outcomes can occur in people of all ages. In 2013, the U.S. Burden of Diseases Collaborators identified lead as one of the top 15 mortality risk factors (and top 10 cardiovascular risk factors) in the

country. In addition, a level of lead exposure below which adverse effects do not occur has not been identified. This suggests that further declines in lead exposure below current-day levels could still yield meaningful benefits in the U.S. population, and the reduction in lead exposures from this proposed rule would result in fewer adverse health outcomes and, in turn, decrease societal costs of treatment. Chapter 5 of the Technical Support Document (USEPA, 2016) for this proposed rule contains additional detailed information on the potential health impacts of lead on both children and adults.

**VIII. Statutory and Executive Orders Reviews**

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

*B. Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2563.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The PRA requires EPA to estimate the burden on manufacturers and primacy agencies of complying with the proposed rule. The information collected as a result of this proposed rule should allow EPA to determine appropriate requirements for specific manufacturers and evaluate compliance with the proposed rule. For the first three years after publication of the final rule in the **Federal Register**, manufacturers will incur burden to conduct the following rule compliance activities:

- Obtaining certification of products from an accredited third party certification body to document compliance with the lead free requirements as set forth in the SDWA.
- Maintaining record costs associated with the initial certification (conducted by an accredited third party certification body) that potable use products meet the requirements of NSF/ANSI Standard 372.
- Preparing the initial certificate of conformity and maintaining records for potable use products that are self-certified by the manufacturer as being lead free.

*Respondents/affected entities:* The respondents include manufacturers of plumbing products intended for potable use and manufacturers of some plumbing products eligible for the “used exclusively” exemption that are physically compatible with potable use products. States and local governments are not impacted by the rule. For the first three years after publication of the

final rule, EPA is not anticipated to incur any reporting or recordkeeping burden for implementation activities and ensuring compliance.

**Respondent's obligation to respond:** Compliance with the final rulemaking regulatory requirements would be mandatory. The authority for these requirements comes from EPA's authority for this proposed rule is section 1450 of the SDWA, 42 U.S.C. 300j-9. It authorizes the EPA Administrator to "prescribe such regulations as are necessary or appropriate to carry out his/her functions under this subchapter."

**Estimated number of respondents:** EPA estimates that 2,193 firms will be affected by the proposed requirements of this regulation.

**Frequency of response:** The requirements of this proposed rule that occur once during the three year ICR period include: Obtaining initial third-party certification or self-certify activities to indicate that a product meets the lead free requirements. Ongoing costs include the third party annual renewal fees, and for all firms annual recordkeeping costs for third party or self-certification. The rule requirement to respond to EPA requests for information is on an ad hoc basis (however, this information collection is not anticipated to occur during the three-year period covered by this ICR).

**Total estimated burden:** Total three-year burden to manufacturers is estimated to be 162,582 to 318,276 hours, therefore the average annual burden number ranges from 54,194 to 106,092 hours. EPA estimated a range of burden (and costs) based on a lower and upper bound estimate of manufacturers that already include product and/or package lead free messaging that comply with the proposed rule requirements, as well as manufacturers that currently use a third party certifying agency. Burden is defined at 5 CFR 1320.3(b).

**Total estimated cost:** The total costs over the three-year period are between \$8.5 and \$12.9 million, or an average of \$2.8 to \$4.3 million per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on EPA's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of

Information and Regulatory Affairs via email to *OIRA\_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 16, 2017. EPA will respond to any ICR-related comments in the final rule.

**C. Regulatory Flexibility Act (RFA)**

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are the manufacturing firms involved in the production of pipe, pipe or plumbing fitting or fixture, flux or solder, which are utilized in public water system or any plumbing in a residential or nonresidential facility or location that provides water for human consumption that meet the SBA's size standards for small businesses. Firms providing these types of plumbing products span fourteen different North American Industrial Classification System (NAICS) categories. The SBA small business definitions used in the analysis of this proposed rule vary across NAICS categories and range from firms with fewer than 500 employees to firm's with fewer than 1,250 employees (See Table XII.1).

TABLE VIII.1—SBA SMALL ENTITY SIZE STANDARDS BY NAICS CODE

NAICS code	SBA size standard
326122 .....	750
332911 .....	750
332913 .....	1000
332919 .....	750
332996 .....	500
332999 .....	750
333318 .....	1000
333415 .....	1250
333911 .....	750
333999 .....	500
334514 .....	750
335222 .....	1250
335228 .....	1000
339991 .....	500

EPA has determined that 1,976 plumbing product manufacturers out of 2,193 plumbing product manufacturers potentially subject to this proposal meet the small business definitions. EPA's analysis of projected impacts on small entities is described in detail in section VII (Economic Impacts). EPA projects less than 2 percent of the 1,976 affected small entities may experience an impact of costs exceeding 1 percent of revenue and no small entities would incur compliance costs exceeding 3 percent of

revenue. Details of this analysis are presented in Chapter 6 of the Technical Support Document, available in the docket, for the proposed rule.

**D. Unfunded Mandates Reform Act (UMRA)**

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The proposed rule places no federal mandates on state, local, or tribal governments. The mandated annual cost to the private sector is estimated to be between \$11.8 and \$18.3 million and the highest single year nominal cost is \$53.4 million which is below the \$100 million UMRA threshold.

**E. Executive Order 13132: Federalism**

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

**F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments**

This action does not have tribal implications as specified in Executive Order 13175. It would not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes. This proposed rule contains no federal mandates for tribal governments and does not impose any enforceable duties on tribal governments. Thus, Executive Order 13175 does not apply to this action.

**G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks**

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it implements specific standards established by Congress in statute. While the executive order does not apply, EPA does anticipate that the labeling requirements associated with

this proposal will limit the inadvertent use of leaded plumbing products, thereby reducing exposure of children to lead in drinking water.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This action involves technical standards. The EPA is proposing a requirement that can be satisfied by, depending on the size of the regulated entity, either self-certifying compliance with the SDWA lead prohibition or by achieving a voluntary standard that mirrors the SDWA requirements, such as the NSF/ANSI 372 standard. While EPA is not specifying a technical standard under this proposed rule, EPA is proposing the use of technical standards that will meet the new definition of lead free as a means of demonstrating compliance with this proposal.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, or indigenous peoples as described in Executive Order 12898 (59 FR 7629, February 16, 1994), because this action does not establish any specific regulatory requirements that would affect these communities. Instead, it is a proposed rule that codifies existing requirements set forth by Congress regarding the allowable levels of lead in plumbing products, and also includes additional provisions intended to aid in the implementation of those requirements.

## IX. References

USHHS, 2012. National Toxicity Program Monograph on Health Effects of Low-level Lead. U.S. Department of Health and Human Services. June 2012. Available on the Internet at: [https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead\\_newissn\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf).

USEPA, 2013a. Summary of the Reduction of Lead in Drinking Water Act and Frequently Asked Questions. December 2013. Available on the Internet at: <https://nepis.epa.gov/Exec/ZipURL.cgi?Dockey=P100M5DB.txt>.

USEPA, 2013b. Final Report: Integrated Science Assessment for Lead. EPA 600-R-10-075F. June 2013. Available on the Internet at: <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=255721>.

USEPA, 2016. Technical Support Document for the Proposed Rule: Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water. EPA 815-R-16-009. December 2016.

## List of Subjects

### 40 CFR Part 141

Environmental protection, Chemicals, Indian—lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

### 40 CFR Part 143

Environmental protection, Chemicals, Indian—lands, Water supply.

Dated: January 4, 2017.

**Gina McCarthy,**  
*Administrator.*

For the reasons set forth in the preamble, EPA proposes to amend title 40 chapter I of the Code of Federal Regulations parts 141 and 143 as follows:

## PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

**Authority:** 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Revise the subpart heading for subpart E to read as follows:

### Subpart E—Special Regulations, Including Monitoring

#### § 141.43 [Removed]

■ 3. Remove § 141.43.

## PART 143—NATIONAL SECONDARY DRINKING WATER REGULATIONS

■ 4. The authority citation for part 143 continues to read as follows:

**Authority:** 42 U.S.C. 300f *et seq.*

■ 5. Revise the part heading for part 143 to read as follows:

## PART 143—OTHER SAFE DRINKING WATER ACT REGULATIONS

■ 6. Add subpart A to read as follows:

### Subpart A—National Secondary Drinking Water Regulations

■ 7. Redesignate §§ 143.1 through 143.4 as subpart A.

#### §§ 143.5–143.10 [Reserved]

■ 8. Reserve §§ 143.5 through 143.10.

■ 9. Add subpart B to read as follows:

### Subpart B—Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

Sec.

143.11 Definitions.

143.12 Definition of lead free and calculation methodology.

143.13 Use prohibitions.

143.14 State enforcement of use prohibitions.

143.15 Introduction into commerce prohibitions.

143.16 Exempt uses and labeling of certain exempt use products.

143.17 Required labeling of products that must meet lead free requirements.

143.18 Required labeling of solder and flux that is not lead free.

143.19 Required certification of products.

143.20 Compliance provisions.

### Subpart B—Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

#### § 143.11 Definitions.

The following definitions apply to this subpart:

*Accredited third party certification body* means those bodies that are accredited by the American National Standards Institute (ANSI) to provide product certification to meet the lead free requirements of not more than a weighted average of 0.25 percent lead content when used with respect to the wetted surfaces, consistent with section 1417 of the Safe Drinking Water Act and § 143.12, such as certification to the NSF/ANSI 372 standard.

*Administrator* means the Administrator of the U.S. Environmental Protection Agency or his or her authorized representative.

*Affiliated* means a person or entity that directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the person or entity specified. Affiliated persons or entities include, but are not limited to: A parent company and all wholly or partially owned subsidiaries of a parent company, or two or more corporations or family partnerships that have overlap in ownership or control.

*Alloy* means a substance composed of two or more metals or of a metal and a nonmetal.

*Coating* means a thin layer of material such as paint, epoxy, zinc galvanization, or other material usually applied by spraying or in liquid form to coat internal surfaces of pipes, fittings or fixtures.

*Drinking water cooler* means any mechanical device affixed to drinking water supply plumbing which actively cools water for human consumption.

*Fitting* means a pipe fitting or plumbing fitting.

*Fixture* means a receptacle or device that is connected to a water supply system or discharges to a drainage system or both. Fixtures used for potable uses shall include, but are not limited to: (1) Drinking water coolers, drinking water fountains, drinking water bottle fillers, dishwashers; (2) plumbed in devices such as point-of-use water treatment devices, coffee makers, and refrigerator ice and water dispensers; and (3) water heaters, water pumps, and water tanks, unless such fixtures are not used for potable uses.

*Flux* means a substance used for helping to melt or join metals such as by removal of oxides and other coatings or residues from the metals before joining by using solder or other means.

*Importer* means any person who introduces into commerce any pipe, any pipe or plumbing fitting or fixture, or any solder or flux that is manufactured by a firm located outside of the United States.

*Introduce into commerce or introduction into commerce* means the sale or distribution of products, or offering products for sale or distribution in the United States.

*Liner* means a rigid lining such as a plastic or copper sleeve that is: (1) Sealed with a permanent barrier to exclude lead-bearing surfaces from water contact; and (2) of sufficient thickness and having physical properties necessary to prevent erosion and cracking for the expected useful life of the product.

*Manufacturer* means a person or entity who: (1) Processes or makes a product; or (2) has products processed or made under a contractual arrangement for distribution using their brand name or trademark.

*Nonpotable services* means all uses of water that are not potable uses.

*Person* means an individual; corporation; company; association; partnership; municipality; or state, federal, or tribal agency (including officers, employees, and agents of any corporation, company, association, municipality, state, tribal, or federal agency).

*Pipe* means a conduit or conductor, tubing or hose.

*Pipe fitting* means any piece (such as a coupling, elbow, washer, or gasket) used for connecting pipe lengths together or to connect other plumbing pieces together or to change direction.

*Plumbing fitting* means a plumbing component that controls the volume and/or directional flow of water, such as kitchen faucets, bathroom lavatory faucets, and valves.

*Potable uses* means services or applications that provide water for human ingestion such as for drinking, cooking, food preparation, dishwashing, teeth brushing, or maintaining oral hygiene.

*Product* means a pipe, fitting, fixture.

*Solder* means a type of metal that is used to join metal parts such as sections of pipe, without melting the existing metal in the parts to be joined. Solder is usually sold or distributed in the form of wire rolls or bars.

*United States* includes its commonwealths, districts, states, tribes, and territories.

*Water distribution main* means a pipe, typically found under or adjacent to a roadway that supplies water to buildings via service lines.

#### **§ 143.12 Definition of lead free and calculation methodology.**

(a) "Lead free" for the purposes of this subpart means:

(1) Not containing more than 0.2 percent lead when used with respect to solder and flux; and

(2) Not more than a weighted average of 0.25 percent lead when used with respect to the wetted surfaces of pipes, pipe fittings, plumbing fittings, and fixtures.

(b) The weighted average lead content of a pipe, pipe fitting, plumbing fitting, or fixture is calculated by using the following formula: For each wetted component, the percentage of lead in the component is multiplied by the ratio of the wetted surface area of that component to the total wetted surface area of the entire product to arrive at the weighted percentage of lead of the component. The weighted percentage of lead of each wetted component is added together, and the sum of these weighted percentages constitutes the weighted average lead content of the product. The lead content of the material used to produce wetted components is used to determine compliance with paragraph (a)(2) of this section. For lead content of materials that are provided as a range, the maximum content of the range must be used.

(c) If a coating, as defined in § 143.11, is applied to the internal surfaces of a pipe, fitting or fixture component, the maximum lead content of both the coating and the alloy must be used to calculate the lead content of the component.

(d) If a liner, as defined in § 143.11, is manufactured into a pipe, fitting or fixture, the maximum lead content of the liner must be used to calculate the lead content of the component.

#### **§ 143.13 Use prohibitions.**

(a) No person may use any pipe, any pipe or plumbing fitting or fixture, any solder or any flux that is not lead free as defined in § 143.12 in the installation or repair of:

(1) Any public water system; or

(2) Any plumbing in a residential or nonresidential facility providing water for human consumption.

(b) Paragraph (a) of this section shall not apply to leaded joints necessary for the repair of cast iron pipes.

#### **§ 143.14 State enforcement of use prohibitions.**

As a condition of receiving a full allotment of Public Water System Supervision grants under section 1443(a) of the Safe Drinking Water Act, states must enforce the requirements of section 1417(a)(1) of Safe Drinking Water Act and § 143.13 through state or local plumbing codes, or such other means of enforcement as the state may determine to be appropriate.

#### **§ 143.15 Introduction into commerce prohibitions.**

It shall be unlawful:

(a) For any person to introduce into commerce any pipe, or any pipe or plumbing fitting or fixture, that is not lead free, except for a pipe that is used in manufacturing or industrial processing;

(b) For any person engaged in the business of selling plumbing supplies in the United States, except manufacturers, to sell solder or flux that is not lead free; and

(c) For any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption.

#### **§ 143.16 Exempt uses and labeling of certain exempt use products.**

The prohibitions in §§ 143.13 and 143.15 shall not apply to the products listed in paragraphs (a) through (c) of this section:

(a) Pipes, pipe fittings, plumbing fittings, or fixtures, including backflow preventers, that are used exclusively for nonpotable services such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption. For the purposes of this subpart, "used exclusively for nonpotable services" means:

(1) The product is incapable of use in potable services (e.g., physically

incompatible with other products that would be needed to convey water for potable uses); or

(2) The product is clearly labeled, on the product, package, container, or tag with a phrase such as: "Not for use with water for human consumption" or another phrase that conveys the same meaning in plain language.

(b) Toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, fire hydrants, service saddles, water distribution main gate valves that are 2 inches in diameter or larger.

(c) Clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps, and emergency drench showers.

**§ 143.17 Required labeling of products that must meet lead free requirements.**

(a) Persons that introduce into commerce products that must meet the lead free requirements of section 1417(a)(3)(A) of the Safe Drinking Water Act and § 143.12 must label such products to indicate that it is in compliance with those requirements. Such labeling must occur by [DATE 3 YEARS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**] or prior to introduction into commerce, whichever occurs later.

(b) Labeling or marking as specified in paragraph (a) of this section must be in accordance with paragraphs (b)(1), (b)(2), and (c) of this section:

(1) Packaged, containerized or tagged products must be labeled or marked on the package, container, or tag with a phrase such as: "Conforms with the lead free requirements of the federal Safe Drinking Water Act," "Lead Free," or similar terms that clearly convey to users that the product is in compliance with the applicable requirements. Products that are not packaged, containerized or tagged are only required to be marked consistent with requirements in paragraph (b)(2) of this section. Shrink wrapping of bulk products solely for the purpose of shipping or storage does not constitute being packaged, containerized, or tagged.

(2) Products must be directly marked by physically stamping, forging, or printing with indelible ink, except as provided in (b)(2)(i) or (b)(2)(ii) of this section. The marking must clearly convey to consumers that the product is lead free, such as "Lead Free," "LF," or certification marks. If the marking is "LF" or another abbreviation, symbol or acronym, the product package, container, or tag must associate that marking with a phrase such as "lead free" or "meets lead free requirements." Product markings should be located

where they are visible after product installation when practical.

(i) If the product is too small for a legible marking in a type face ranging from approximately 8 point to 14 point depending on the method of marking and roughness of product surface, only a product package, container or tag must be labeled or marked.

(ii) If the visible marking on installed products will adversely impact the visual appeal to consumers of the finished product, the product may be marked in a location not visible after installation.

(c) For products certified by accredited third party certification bodies, labeling or marking on the product, package, container, tag or some combination of these locations must include:

(1) The logo or name of the certification body as specified by the specific certification body; and

(2) The specific certification body's required identifier text to convey lead free or low lead content.

**§ 143.18 Required labeling of solder and flux that is not lead-free.**

Solder and flux that is not "lead free" as defined in § 143.12(a)(1) must bear a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption.

**§ 143.19 Required certification of products.**

(a) Manufacturers or importers that introduce into commerce products that must meet the lead free requirements of section 1417 of the Safe Drinking Water Act and § 143.12 must ensure that the products are certified to be in compliance as specified in paragraphs (b) and (c) of this section by [DATE 3 YEARS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**] or prior to product introduction into commerce, whichever occurs later. Such manufacturers or importers must maintain documentation to substantiate the certification.

(b) Certification of products must be obtained by manufacturers or importers from an accredited third party certification body, except as provided in paragraph (c) of this section.

(1) Products certified by an accredited third party certification body must be labeled or marked as specified in § 143.17(c).

(2) The manufacturer or importers must keep records for all products certified by an accredited third party certification body that include at a minimum: Documentation of

certification, dates of certification and expiration. This documentation must be provided upon request to the Administrator as specified in § 143.20(b).

(c) Manufacturers having fewer than 100 employees or importers sourcing products from or representing manufacturers having fewer than 100 employees may elect to self-certify products in lieu of obtaining certification from an accredited third party certification body. The number of employees includes any persons employed by the manufacturer and any of its affiliated entities. The number of employees must be calculated by averaging the number of persons employed, regardless of part-time, full-time or temporary status by an entity and all of its affiliated entities for each pay period over the entity's latest 12 calendar months, or averaged over the number of months in existence if less than 12 months. Such manufacturers or importers electing to self-certify products must comply with paragraphs (d) through (g) of this section.

(d) In order for eligible manufacturers or importers to self-certify products, such manufacturers or importers must attest that products are in compliance by developing and maintaining a "certificate of conformity." The certificate of conformity must be:

(1) Signed by a responsible corporate officer, a general partner or proprietor, or an authorized representative of a responsible corporate officer, general partner or proprietor; and

(2) Posted to a Web page with continuing public access in the United States.

(e) The certificate of conformity must be in English and include:

(1) Contact information for the manufacturer or importer to include:

- (i) The entity or proprietor name,
- (ii) Street and mailing addresses,
- (iii) Phone number, and
- (iv) Email address.

For products imported into the United States, the contact information must also be included for the manufacturer;

(2) A brief listing of the products to include, when applicable, unique identifying information such as model names and numbers;

(3) A statement attesting that the products meet the lead free requirements of the Safe Drinking Water Act and 40 CFR part 143, subpart B and also that the manufacturer or importer is eligible to self-certify the product consistent with this regulation;

(4) A statement indicating how the manufacturer or importer verified conformance with the Safe Drinking

Water Act and 40 CFR part 143, subpart B; and

(5) The signature, date, name and position of the signatory; and if the signatory is an authorized representative of a responsible corporate officer, a general partner or proprietor, the name and position of the responsible corporate officer, a general partner or proprietor.

(f) Manufacturers or importers that self-certify products must maintain, at a primary place of business within the United States, certificates of conformity and sufficient documentation to confirm that products meet the lead free requirements of this subpart. Sufficient documentation may include: Detailed schematic drawings of the products indicating dimensions, calculations of the weighted average lead content of the product, lead content of materials used in manufacture and other documentation used in verifying the lead content of a plumbing device. This documentation and certificates of conformity must be provided upon request to the Administrator as specified in § 143.20(b).

(g) The certificate of conformity and documentation must be completed prior to a product's introduction into commerce.

#### § 143.20 Compliance provisions.

(a) Noncompliance with the Safe Drinking Water Act or this subpart may be subject to enforcement. Enforcement actions may include seeking injunctive relief, civil or criminal penalties.

(b) The Administrator may, on a case-by-case basis, request any information deemed necessary to determine whether a person has acted or is acting in compliance with section 1417 of the Safe Drinking Water Act and this subpart. Such information requested must be provided to the Administrator at a time and in a format as may be reasonably determined by the Administrator.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 702

[EPA-HQ-OPPT-2016-0636; FRL-9957-74]

RIN 2070-AK23

### Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a risk-based screening process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The proposed rule describes the processes for identifying potential candidates for prioritization, selecting a candidate, screening that candidate against certain criteria, formally initiating the prioritization process, providing opportunities for public comment, and proposing and finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under recent amendments to TSCA.

**DATES:** Comments must be received on or before March 20, 2017.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0636, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

*For technical information contact:* Ryan Schmit, Immediate Office, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-0610; email address: [schmit.ryan@epa.gov](mailto:schmit.ryan@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

###### A. Does this action apply to me?

This proposed rule does not propose to establish any requirements on persons or entities outside of the Agency. This action may, however, be of interest to entities that are or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

###### B. What action is the agency taking?

EPA is proposing to establish the internal processes and criteria by which EPA will identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time.

###### C. Why is the agency taking this action?

This rulemaking is required by TSCA section 6(b)(1)(A). Prioritization of chemical substances for further evaluation will ensure that the Agency's limited resources are conserved for those chemical substances most likely to present risks, thereby furthering EPA's overall mission to protect health and the environment.

###### D. What is the agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b), 15 U.S.C. 2605(b). See also the discussion in Units II.A and B.

###### E. What are the estimated incremental impacts of this action?

This is a proposed rule that would establish the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It would not establish any requirements on persons or entities outside of the Agency. EPA did not, therefore, estimate potential incremental impacts from this action.

###### F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that



you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## II. Background

### A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” (Pub. L. 114–182), which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA’s Web site at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were “grandfathered in” with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemical substances, and manage identified risks. Through a

combination of new authorities, a risk-based safety standard, mandatory deadlines for action, and minimum throughput requirements, TSCA effectively creates a “pipeline” by which EPA will conduct existing chemical substances review and management. This new pipeline—from prioritization to risk evaluation to risk management (when warranted)—is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Prioritization is the initial step in this process.

### B. Statutory Requirements for Prioritization

TSCA section 6(b)(1) requires EPA to establish, by rule, the process and criteria for prioritizing chemical substances for risk evaluation. Specifically, the law requires EPA to establish “a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.” TSCA sections 6(b)(1) through (3) provide further specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either High-Priority Substances or Low-Priority Substances. The statutory requirements related to prioritization are described in further detail in this unit.

1. *Prioritization Steps.* Based on TSCA sections 6(b)(1) through (3), EPA is proposing to include four steps or phases in prioritization: (1) Pre-Prioritization, (2) Initiation, (3) Proposed Designation, and (4) Final Designation. During the Pre-Prioritization phase, EPA is proposing to apply the statutory preferences in TSCA section 6(b)(2), along with other criteria, to narrow the pool of potential candidates, and identify a single chemical substance (or category of chemical substances) to screen against the statutory criteria in TSCA section 6(b)(1)(A). Aside from the statutory preferences listed, the law does not direct or limit EPA in how it is to ultimately select a chemical substance on which to initiate prioritization, requiring only that the process be “risk-based.” At the Initiation step, EPA must announce a candidate chemical substance and give the public a 90-day

comment period to submit relevant information. 15 U.S.C. 2605(b)(1)(C)(i). At the Proposed Designation step, EPA must propose to designate a chemical substance as either a High-Priority Substance or a Low-Priority Substance, publish the proposed designation and the information, analysis, and basis used to make the designation, and take public comment a second time for 90 days. 15 U.S.C. 2605(b)(1)(C)(ii). At Final Designation, EPA must either finalize a High-Priority Substance designation and initiate a risk evaluation, or finalize a Low-Priority Substance designation in which case it will not conduct a risk evaluation on the chemical substance unless and until information leads EPA to revisit that priority designation. 15 U.S.C. 2605(b)(3)(A) and (B).

2. *Screening criteria and statutory preferences.* The statute defines a High-Priority Substance as one that the Administrator concludes, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the Administrator. 15 U.S.C. 2605(b)(1)(B)(i). Conversely, the law specifies that a Low-Priority Substance is one that the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for designating a chemical substance a High-Priority Substance. 15 U.S.C. 2605(b)(1)(B)(ii).

In designating the priority of a chemical substance, EPA must screen a candidate chemical substance against certain criteria specified in TSCA section 6(b)(1)(A). These include the hazard and exposure potential of the chemical substance (*e.g.*, persistence and bioaccumulation, potentially exposed or susceptible subpopulations, and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed. EPA interprets “significant changes in” conditions of use to have relevance primarily in the context of revising a priority designation. With respect to an initial prioritization decision, any changes in use that have occurred in the past would already be captured by the concept of “conditions of use,” as defined in TSCA section 3.

The results of this screen will help inform EPA's proposed priority designation. However, given that the statutory deadlines are triggered at the initiation of prioritization, and that EPA will want to have a good understanding of the chemical substance before triggering those deadlines, EPA will consider these screening criteria earlier in the process. As discussed in more detail in Unit III., EPA is therefore proposing to include the screening review in the rule as part of the pre-prioritization phase.

In designating High-Priority Substances, EPA is to give preference to chemical substances that are listed in the 2014 Update of the TSCA Work Plan for Chemical Assessments (Ref. 1) that: (1) Have persistence and bioaccumulation scores of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. 15 U.S.C. 2605(b)(2)(D). The law further requires that 50% of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that, at least at the outset of the program, EPA will need to draw at least 50% of High-Priority Substance designations from the same list. 15 U.S.C. 2605(b)(2)(B).

3. *Metals and metal compounds.* When prioritizing metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 2) (or a successor document that addresses appropriate considerations for conducting a risk assessment on a metal or metal compound and is peer reviewed by the Science Advisory Board). 15 U.S.C. 2605(b)(2)(E). However, during the prioritization process, EPA will not be conducting chemical risk assessments; and, consequently, much of this guidance will not be directly relevant. EPA interprets this provision to ensure that the analysis and considerations during the prioritization process take into account the special attributes and behaviors of metals and metal compounds that are relevant to judgments of risk. For example, this might include consideration of the document's Key Principles that differentiate inorganic metals and metal compounds from organic and organometallic compounds, and their unique attributes, properties, issues, and processes. Because EPA will not conduct risk assessments on metals or metal compounds for purposes of prioritization, EPA will not refer to sections that provide guidance on how to incorporate the Key Principles into risk assessments.

4. *Timeframe.* TSCA requires that the prioritization process last between nine and twelve months. 15 U.S.C. 2605(b)(1)(C). This timeframe takes on particular significance, given that the statute does not authorize EPA to "pause" or delay the prioritization once it has been initiated, and that a final High-Priority Substance designation results in the chemical substance moving immediately into a risk evaluation process that must be generally completed within three years. 15 U.S.C. 2605(b)(4)(G).

5. *Opportunities for public participation.* As already mentioned, TSCA requires EPA to provide two 90-day public comment periods during prioritization—one following initiation, and a second following a proposed designation. 15 U.S.C. 2605(b)(1)(C)(i) and (ii). TSCA further requires that EPA include a process for extending the comment deadline for up to three months in order to receive or evaluate information coming from a TSCA section 4 test order. 15 U.S.C. 2605(b)(1)(C)(iii). These public comment periods, coupled with the nine month minimum timeframe for prioritization, ensure that the public will be on notice of EPA's intention to further evaluate a chemical's risks and will have opportunity to engage early in the process before the risk evaluation has started.

6. *Default to High-Priority Substance Designation.* If, after prioritization has been initiated, the public has been given an opportunity to submit relevant information, and EPA has extended the comment period pursuant to TSCA section 6(b)(1)(C)(iii) in order to receive or evaluate additional information, EPA determines that the available information is insufficient to enable the designation of the chemical substance as a Low-Priority Substance, the statute requires EPA to propose a High-Priority Substance designation. 15 U.S.C. 2605(b)(1)(C)(iii). Based in part on this provision, and as discussed further in Unit III, EPA is proposing to require a default-to-high in all cases in which insufficient information exists to designate the chemical as a Low-Priority Substance at both the proposed and final designation.

7. *Initial ten chemicals for risk evaluation.* TSCA requires EPA to, within six months of enactment, ensure that risk evaluations are being conducted on ten chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments, and to publish a list of those chemical substances during that same period. 15 U.S.C. 2605(b)(2)(A). The initial ten chemical substances are

not subject to the prioritization process or the procedures in this rule. However, completion of these risk evaluations triggers the ongoing designation requirement discussed in Unit II.B.8.

8. *Ongoing designations.* Upon completion of a risk evaluation (other than those requested by a manufacturer pursuant to TSCA section 6(b)(4)(C)(ii)), EPA must designate at least one additional High-Priority Substance to take its place. 15 U.S.C. 2605(b)(2)(C). Because designation as a High-Priority Substance results in the chemical substance moving immediately to risk evaluation, this provision prevents the number of existing chemical substances undergoing risk evaluation from ever decreasing over time. In addition, EPA must designate at least twenty chemical substances as High-Priority Substances by three and one half years after enactment, effectively doubling the number of chemical substances in the review pipeline. 15 U.S.C. 2605(b)(2)(B). The statute also requires that at least twenty chemical substances be designated as Low-Priority Substances by three and one half years after enactment, but without a comparable requirement to continue designating additional Low-Priority Substances after that. 15 U.S.C. 2605(b)(2)(B), (b)(3)(C). Although EPA must continue to prioritize and evaluate chemical substances "at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines," this provision does not modify the minimum throughput or other ongoing designation requirements for High-Priority Substances. 15 U.S.C. 2605(b)(2)(C). It does, however, suggest that EPA must have adequate resources should EPA plan to designate more than twenty chemical substances as High-Priority Substances at any given time.

9. *Revision of designation.* TSCA allows the Administrator to revise the designation of a Low-Priority Substance to a High-Priority Substance "based on information made available to the Administrator." 15 U.S.C. 2605(b)(3)(B). This provision does not restrict the basis for a revision to the discovery or receipt of new information. For example, EPA could also justify a revision based on information that was available but was not considered at the time of the original prioritization decision, or information that was considered but which EPA now views differently as a result of changes in scientific understanding (e.g., changes in scientific understanding of how a chemical can enter or interact with the human body).

10. *Other relevant statutory requirements.* TSCA imposes new

requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to “. . . reduce and replace, to the extent practicable, [ . . . ] the use of vertebrate animals in the testing of chemical substances . . .” and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA use certain scientific standards and base those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the prioritization of chemical substances, EPA is not obliged to include them in this proposed rule. By their express terms, these statutory requirements apply to EPA’s decisions under TSCA section 6, without the need for regulatory action. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements “by rule;” it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions. *E.g., United States v. Storer Broadcasting Co.*, 351 U.S. 192 (1956).

A number of stakeholders raised questions as to whether EPA should define a number of important terms in this rule (*e.g.*, “best available science”, “weight-of-the-evidence”, “sufficiency of information”, “unreasonable risk”, and “reasonably available information”). Many of the terms used in the proposed rule are not novel concepts and are already in use, and their meaning is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases “best available science”, “weight-of-the-evidence”, and “sufficiency of information” can be found in EPA’s Risk Characterization Handbook (Ref. 3), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility and responsiveness of the Agency to quickly adapt to and implement changing science. The Agency intends to use existing guidance definitions and to update definitions and guidance as necessary.

While EPA is seeking public comment on all aspects of this proposed rule, the Agency is specifically requesting public input on this issue. The Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable.

#### *C. Prioritization Under the 2012 TSCA Work Plan Methodology*

Prioritization of chemical substances for review is not a novel concept for the Agency. In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemical substances for near-term review and assessment under TSCA (Ref. 4). EPA also published an initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program in 2012 (Ref. 5), and an updated list of chemical substances for further assessment in 2014 (Ref. 1). The process for identifying these chemical substances was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics.

Congress expressly recognized the validity of EPA’s existing prioritization methodology for the TSCA Work Plan. For example, the law requires that EPA give certain preferences to chemical substances listed on the 2014 Update to the TSCA Work Plan. 15 U.S.C. 2605(b)(2)(D). Moreover, the law requires that at least 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan. 15 U.S.C. 2605(b)(2)(B). The statutory screening criteria in TSCA section 6(b)(1)(A) also significantly overlaps with the considerations in the Work Plan methodology (*e.g.*, persistence, bioaccumulation, toxicity, carcinogenicity, etc.).

However, there are a number of key differences between EPA’s TSCA Work Plan process and the prioritization process that TSCA now requires. First, the Work Plan process involved culling through thousands of chemical substances to create a list that EPA could, over time and without prescribed deadlines, focus its limited resources on. The TSCA Work Plan did not require EPA to assess listed chemical substances, and included no deadlines

for completing risk assessments or addressing identified risks. Prioritization under this proposed rule will involve a similar culling, but upon designating a chemical substance as a High-Priority Substance, the Agency must start a risk evaluation, and generally complete that evaluation within a specified amount of time. If EPA determines in the risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must also initiate a risk management rulemaking subject to statutory deadlines. 15 U.S.C. 2605(c). As such, EPA will need to be judicious in selecting the chemical substances that go into prioritization.

Further, while chemical substances listed on the TSCA Work Plan were likely to be well-characterized for hazard and have at least some information indicating potential exposure, Work Plan chemical substance assessments have generally focused on specific chemical uses. Given the statutory deadlines, EPA generally intends to ensure it has a more complete set of data upfront that would allow EPA to evaluate a chemical substance under all conditions of use (a broader scope) within the statutory deadlines. For chemical substances with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization.

Finally, the TSCA Work Plan process focused solely on identifying potential high risk chemical substances for further review. Because the statute also requires the identification of Low-Priority Substances—those chemical substances that EPA has determined, based on sufficient evidence, do not warrant further review at the time—EPA will need to undertake new and different analyses than it has done to date under the TSCA Work Plan.

While EPA has drawn from the TSCA Work Plan methodology and EPA’s experience in implementing that process in developing this proposed rule, EPA is proposing to tailor the process for prioritization to the specific requirements in the new statute.

#### *D. Stakeholder Involvement*

On August 10, 2016, EPA held a one day public meeting to hear from stakeholders to better understand their viewpoints on the development of the prioritization rule. The meeting began with a presentation from EPA on how the Agency has prioritized chemicals for further review under the TSCA Work Plan methodology. The remainder of the day was reserved for public comment. Commenters had approximately four

minutes to present their comments orally and there was a total of 28 oral comments on the prioritization rule. Further information is available on EPA's Web site at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control>.

Stakeholders were also able to provide written comments. EPA received 50 written comments on the prioritization rule, although many of those who presented orally also submitted written versions as well. These comments and a transcript of the meeting are accessible in the meeting's docket, identified by Docket ID No. EPA-HQ-OPPT-2016-0399, available online at <https://www.regulations.gov/>.

The commenters included representatives from industry, environmental groups, academics, private citizens, trade associations, and health care representatives, and provided a diversity of perspectives. Overall, there was a general expression of support for the new law and EPA's inclusive approach to implementation to date. Most groups agreed that the prioritization rule had the potential to increase transparency in EPA's chemical substance review and management process, and urged the Agency to work towards this goal.

A number of commenters suggested codifying specific details in the rule, such as a system for scoring and ranking chemical substances; a listing of the specific hazard and exposure information upon which EPA will base prioritization decisions; and definitions of terms referenced in the statute like "weight of evidence" and "best available science." Others encouraged EPA to keep the rules focused on a framework for general process, to retain Agency discretion where appropriate, and to reserve specific scientific considerations for Agency guidance.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the Agency's proposed process for chemical substance prioritization as presented in this document.

### III. Summary of Proposed Rule

This proposed rule incorporates all of the elements required by statute, but also supplements those requirements with additional criteria the Agency expects to consider, some clarifications for greater transparency, and additional procedural steps to ensure effective implementation. Specific components of the approach are discussed in this unit. EPA requests comments on all aspects of this proposed rulemaking.

#### A. Policy Objective

The prioritization process under TSCA is the principal gateway to risk evaluation. EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment. As a general matter, the overall objective of the process should be to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first. EPA may also consider the relative hazard and exposure of a potential candidate's likely substitute(s) in order to avoid moving the market to a chemical substance of equal or greater risks. However, the prioritization process is not intended to be an exact scoring or ranking exercise and EPA is not proposing such a system in this rule. The precise order in which EPA identifies High-Priority Substances (all of which must meet the same statutory standard) should not be allowed to slow the Agency's progress towards fully evaluating the risks from those chemical substances. Further, the level of analysis necessary to support an exact ranking system is not appropriate at the prioritization stage, where the sole outcome is a decision on whether EPA will further evaluate the chemical substance. EPA intends to conserve its resources and the Agency's deeper analytic efforts for the actual risk evaluation. This policy objective is stated directly in the proposed rule.

Low-Priority Substance designations serve some of the same policy objectives. Although the statute does not require EPA to designate more than twenty Low-Priority Substances, doing so ensures that chemical substances with clearly low hazard and exposure potential are taken out of consideration for further assessment, thereby conserving resources for the chemical substances with the greatest potential risks. There is also value in identifying Low-Priority Substances as part of this process, as it gives the public notice of chemical substances for which potential risks are likely low or nonexistent, and industry some insight into which chemical substances are likely not to be regulated under TSCA.

#### B. Scope of Designations

EPA will designate the priority of a "chemical substance," as a whole, under this established process, and will not limit its designation to a specific use or subset of uses of a chemical substance. EPA is proposing this in response to clear statutory directives: The relevant provisions of TSCA section 6 repeatedly refer to both the

designation and evaluation of "chemical substances" under the "conditions of use." "Conditions of use" are broadly defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. 2602.

Although some commenters at the public meeting suggested that the prioritization process should allow EPA to designate a specific use of a chemical substance as a High-Priority Substance or a Low-Priority Substance, EPA does not interpret the statute to support such an interpretation. To the contrary, the addition of the phrase "conditions of use" (emphasis added) was intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a comprehensive approach to chemical substance management. While EPA clearly retains some discretion in determining those conditions of use, as a matter of law, EPA considers that it would be an abuse of that discretion to simply disregard known, intended, or reasonably foreseen uses in its analyses.

#### C. Timeframe

As discussed in Unit II., TSCA section 6(b)(1)(C) requires that the prioritization process last between nine and twelve months. EPA is proposing in this rule that initiation of the prioritization begins upon publication of a notice in the **Federal Register** that identifies a chemical substance for prioritization and provides the results of the screening review. The process is complete upon publication of a notice in the **Federal Register** announcing a final priority designation. Accordingly, the proposed rule specifies that the process—from initiation to final designation—shall last between 9 and 12 months.

This timeframe serves dual purposes. The minimum 9-month timeframe ensures that the general public; potentially-affected industries; state, tribal and local governments; environmental and health non-governmental organizations; and others have ample notice of upcoming federal action on a given chemical substance, and opportunity to engage with EPA early in the process. The 12-month maximum timeframe, coupled with the default-to-high provision discussed later, keeps the existing chemical substances review pipeline in a forward motion, and prevents EPA from getting mired in analysis before ever reaching the risk evaluation step.

#### D. Categories of Chemical Substances

TSCA section 26 provides EPA with authority to take action on categories of chemical substances. 15 U.S.C. 2625(c). “Category of Chemical Substances” is defined at 15 U.S.C. 2625(c)(2)(A). Although the proposed rule most often references “chemical substances,” EPA is also proposing to include a clear statement in the regulation that nothing in the proposed rule shall be construed as a limitation on EPA’s authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances.

#### E. Chemicals Subject to Prioritization

Generally, all chemical substances listed on the TSCA Inventory are subject to prioritization. TSCA contemplates that, over time, all chemical substances on the TSCA Inventory will be prioritized into either High- or Low-Priority Substances, and that all High-Priority Substances will be evaluated. EPA notes that chemical substances newly added to the TSCA Inventory following EPA’s completion of pre-manufacture review under section 5 of TSCA (15 U.S.C. 2604) are also candidates for prioritization, although EPA expects that such chemical substances are not likely to be High-Priority candidates in light of the risk-related determination that the Agency must make pursuant to TSCA section 5(a)(3).

TSCA further requires EPA to go through a separate process of determining which chemical substances on the TSCA Inventory are still actively being manufactured, and EPA has initiated a separate rulemaking for that purpose (RIN 2070-AK24). This distinction will inform EPA’s exposure judgments during the prioritization process. However, there is nothing in TSCA that prohibits EPA from initiating the prioritization process on an “inactive” chemical substance and ultimately designating that chemical substance as either a High-Priority Substances (e.g., if exposures of concern arise from ongoing uses) or Low-Priority Substance.

#### F. Pre-Prioritization Considerations

As discussed earlier, TSCA requires that EPA establish a process, including criteria for designating a chemical substance as either a High-Priority Substances or Low-Priority Substance. 15 U.S.C. 2605(b)(1). Aside from the statutory preferences for chemical substances on the 2014 Update to the TSCA Work Plan (Ref. 1), the statute

leaves EPA with broad discretion to choose which chemical substance to put into that process. Accordingly, this proposed rule includes a discussion of the criteria EPA expects to use to cull through the chemical substances on the TSCA Inventory. These include criteria that will be used to identify potential candidates for High-Priority Substances or Low-Priority Substances, and that describe how the extent of available information on potential candidates will affect whether they are selected for prioritization.

For example, in identifying potential candidates for High-Priority Substance designations, EPA is proposing to seek to identify chemical substances where available information suggests that the chemical substance may present a hazard and that exposure is present under “one or more conditions of use,” but where an “unreasonable risk” determination cannot be made without a more extensive or complete assessment in a risk evaluation. EPA interprets the statutory definition of a High-Priority Substance (“ . . . may present an unreasonable risk [ . . . ] because of a potential hazard and a potential route of exposure . . .”) to set a fairly low bar, and EPA expects that a large number of chemical substances will meet this definition. Although EPA will prioritize a “chemical substance” as a whole, EPA may base its identification of a potential candidate as a High-Priority Substance, and ultimately the proposed designation, on a single condition of use, provided the hazard and exposure associated with that single use support such a designation. This proposal is based on the statutory definition of a High-Priority Substance, which is clear that the standard for the chemical as a whole can be met based on a single condition of use (“ . . . because of a potential hazard and a potential route of exposure . . .”).

Conversely, in identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for “all conditions of use” are so low that EPA can confidently set that chemical substance aside without doing further evaluation. By comparison, then, TSCA’s definition of Low-Priority Substance (“ . . . based on sufficient information, such *substance* does not meet the standard for [ . . . ] a high-priority substance . . .”) is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-Priority Substance standard.

Consequently, EPA expects it will be more difficult to support such designations. Unlike High-Priority Substances, EPA will not be able to designate a chemical substance as a Low-Priority Substance without first looking at all of the conditions of use. While not determinative, EPA believes that its Safer Chemicals Ingredients List (SCIL) (Ref. 6) will be a good starting point for identifying potential candidates for Low-Priority Substance designations.

EPA is also proposing to include the following list of additional exposure and hazard considerations that can be used to narrow the field of potential candidates: (1) Persistent, bioaccumulative, and toxic; (2) Used in children’s products; (3) Used in consumer products; (4) Detected in human and/or ecological biomonitoring programs; (5) Potentially of concern for children’s health; (6) High acute and chronic toxicity; (7) Probable or known carcinogen; (8) Neurotoxicity; or (9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency. These criteria are drawn from EPA’s 2012 TSCA Work Plan methodology (Ref. 4), which, as discussed earlier, was the process EPA had been using to prioritize chemical substances for assessment under TSCA. EPA will evaluate one or more of these nine considerations, and chemical substances that meet one or more of these criteria may be identified as potential candidates for High-Priority Substance designations. For example, if a chemical substance is highly toxic and used in consumer products, EPA may wish to consider that chemical substance as a potential High-Priority Substance candidate. EPA may also choose to identify potential candidates based on other criteria that suggest the chemical substance may otherwise present a human health or environmental concern, as contemplated in the “catch-all” provision (9). The fact that a chemical substance meets one of these criteria is not determinative of an outcome, including whether or not EPA will select the chemical substance to go into the prioritization process and/or the priority designation that the chemical substance will ultimately receive. Conversely, chemical substances that meet none of these criteria may be good potential candidates for Low-Priority Substance designation. The considerations are intended to serve as a general guide for the Agency, based on EPA’s current understanding of important considerations regarding

potential chemical risk. It should also be noted that while these considerations are drawn from EPA's 2012 Work Plan methodology (Ref. 4), EPA will apply them differently for prioritization. In the TSCA Work Plan context, only chemical substances that met these initial criteria were eligible for listing on Work Plan. For purposes of prioritization under TSCA, the considerations do not determine eligibility, but rather are designed to help EPA to narrow its focus.

### G. Information Availability

Another key consideration in the pre-prioritization phase is the existence and availability of risk-related information on a candidate or potential candidate chemical substance. Because EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, immediately initiate a risk evaluation for High-Priority Substance, and complete the risk evaluation within three years of initiation, EPA cannot assume that it will be able to require the generation of critical information during these time frames. Furthermore, the statute does not grant EPA the discretion to significantly delay either of these processes, pending development of information. Consequently, prior to initiating the prioritization process for a chemical substance, EPA will generally review the available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete both prioritization and risk evaluation processes. As part of such an evaluation, EPA expects to consider the quality, objectivity, utility, and integrity of the available information. To the extent the information is not currently available or is insufficient, EPA will determine whether or not information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. The proposed rule makes it clear that sufficiency of available information is likely to be a crucial factor in the selection of the chemical substances that EPA chooses to put into the prioritization process.

As noted, if information gaps are identified *during* the prioritization or risk evaluation processes, EPA expects that it could be difficult to require the development of necessary chemical substance information, and receive, evaluate, and incorporate that information into analyses and decisions within the statutory timeframes. Tests necessary for risk evaluation, for example, could take months or years to develop and execute, plus additional

time for EPA to issue the order or rule, and to collect, review and incorporate the new information. To avoid such a scenario, EPA believes that it will need to do a significant amount of upfront data gathering and review. This approach ensures that EPA stays on track to meet relevant statutory deadlines—particularly those for risk evaluation.

The proposed rule makes clear that EPA generally expects to use this new authority, as appropriate and necessary, to gather the requisite information prior to initiating prioritization. This could include, as appropriate, TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c), to develop needed information.

Given the importance of ensuring that sufficient information is available to conduct the prioritization and risk evaluation processes, EPA is proposing to include this consideration during the earliest stage in the process: During the identification of potential candidates. However, this criterion remains relevant even after EPA has selected a candidate and screened that chemical substance against the statutory criteria in TSCA section 6(b)(1)(A). Thus, if at any time prior to the publication of a notice in the **Federal Register** initiating prioritization, EPA determines that more information will be necessary to support a prioritization designation or a subsequent risk evaluation, EPA can choose not to initiate prioritization for that chemical substance pending development of additional information.

### H. Selection and Screening of a Candidate Chemical Substance

As noted in Unit II., TSCA requires that EPA give preference to chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that (1) have a Persistence and Bioaccumulation Score of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. TSCA section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that EPA will need to draw at least 50 percent of High-Priority Substance candidates from the same list. By operation of the statute, TSCA requires that all TSCA Work Plan chemical substances eventually be prioritized. However, it is premature to presume that those chemical substances will necessarily be prioritized as High-Priority Substances, or that EPA would find unreasonable risk.

Aside from these statutory preferences, however, TSCA does not limit how EPA must ultimately select a candidate chemical substance to put into the prioritization process. EPA is proposing that it will select a candidate—for either High-Priority Substances or Low-Priority Substance—based on the policy objectives described in Unit III.A. and the pre-prioritization considerations described in Unit III. F. and G. The development of the proposed rule, including these policy objectives, considerations and criteria, was informed by EPA's experience implementing the 2012 TSCA Work Plan methodology, which has been the Agency's primary tool for identifying candidate chemical substances for further assessment under TSCA. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback *during* the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase. Further, given EPA's objective to avoid simply moving the market to substitute chemical substances of equal or greater risks, EPA requests comment on whether and how information on the availability of chemical substitutes should be taken into account during this phase of the prioritization process.

Once a single candidate chemical substance (or category of chemical substances) is selected, EPA will screen the selected candidate against the specific criteria and considerations in TSCA section 6(b)(1)(A). Those criteria and considerations are: (1) The chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume. Because TSCA does not prohibit EPA from expanding the statutory screening criteria, the proposed rule also provides an additional criterion: (7) Any other risk-based criteria relevant to the

designation of the chemical substance's priority, in EPA's discretion. This final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback during the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase.

The screening review is not a risk evaluation, but rather a review of available information on the chemical substance that relates to the screening criteria. EPA expects to evaluate all relevant sources of information while conducting the screening review, including, as appropriate, the hazard and exposure sources listed in Appendices A and B of the 2012 TSCA Work Plan methodology (Ref. 4). Ultimately, the screening review and other considerations during the pre-prioritization phase are meant to inform EPA's decisions on (1) whether to initiate the prioritization process on a particular chemical substance, and (2) once initiated, the proposed designation of that chemical substance as either a High-Priority Substance or Low-Priority Substance.

#### *I. Initiation of Prioritization*

The prioritization process officially begins, for purposes of triggering the nine to twelve month statutory timeframe, when EPA publishes a notice in the **Federal Register** identifying a chemical substance for prioritization. The proposed rule also specifies that EPA will publish the results of the screening review in the **Federal Register**, describing the information, analysis and basis used to conduct that review and providing in the docket copies of relevant information not otherwise protected as confidential business information under TSCA section 14. Publication of the notice in the **Federal Register** also initiates a 90-day public comment period. For each chemical substance, EPA will open a docket to facilitate receipt of public comments and access to publicly available information throughout this process. Interested persons can submit information regarding the results of the screening review or any other

information relevant to the chemical substance. Of particular interest to EPA will be information related to "conditions of use" that are missing from the screening results. EPA will consider all relevant information received during this comment period. Consistent with TSCA section 6(b)(1)(C)(iii), the proposed rule further allows EPA to extend this initial public comment period for up to 3 months to receive and/or evaluate information developed from a test order, commensurate with EPA's need for additional time to receive and/or evaluate this information. As a practical matter, EPA is unlikely to often extend this initial public comment, given EPA's intention to ensure that all or most of the necessary information is available before initiating the prioritization process. Further, a three month window would not often provide a sufficient time to gather, let alone consider, new test data for the prioritization process. This is generally expected to be the case even with the authority to more quickly collect such information under the new test order authority in TSCA section 4.

#### *J. Proposed Priority Designation*

Based on the results of the screening review, relevant information received from the public in the initial comment period, and other information as appropriate, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, as those terms are defined in TSCA. In making this proposed designation, as directed by the statute, EPA will not consider costs or other non-risk factors.

This proposed rule provides that EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a second comment period of 90 days, during which time the public may submit comments on EPA's proposed designation. EPA proposes to use the same docket for this step of the process. Because the supporting documentation for a proposed High-Priority Substance designation is likely to foreshadow what will go into a scoping document for risk evaluation, EPA will be particularly interested in early comments on the accuracy of scope-related information such as the chemical's "conditions of use."

In the event of insufficient information at the proposed designation step, EPA is proposing to designate a chemical substance as a High-Priority Substance. EPA expects this situation to

occur infrequently based on its application of the criteria and considerations during the pre-prioritization phase. However, if for some reason the information available to EPA is insufficient to support a proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period, consistent with the statute, the proposed rule requires EPA to propose to designate the chemical substance as a High-Priority Substance. The statute requires that the prioritization process lead to one of two outcomes by the end of the 12-month deadline: A High-Priority Substance designation or a Low-Priority Substance designation. 15 U.S.C. 2605(b)(1)(B). There is no third option to allow EPA to either require the development of additional information or otherwise toll this deadline. Further, the statute specifically requires that a Low-Priority Substance designation be based on "information sufficient to establish" that a chemical substance meets the definition. 15 U.S.C. 2605(b)(1)(B)(ii). There is no comparable statutory requirement for High-Priority Substance designations. 15 U.S.C. 2605(b)(1)(B)(i). It is also relevant that the effect of designating a chemical as High-Priority Substance is that EPA further evaluates the chemical substance; by contrast, a Low-Priority Substance designation is a final Agency determination that no further evaluation is warranted—a determination that constitutes final agency action, subject to judicial review. 15 U.S.C. 2618(a)(1)(C)(i).

The logical implication of this statutory structure is that scientific uncertainty in this process (including as a result of insufficient information) is to weigh in favor of a High-Priority Substance designation, as it is merely an interim step that ensures that the chemical will be further evaluated. EPA's proposal would also ensure that this process would not create any incentives for parties to withhold readily available information, or inadvertently discourage the voluntary generation of data, as could occur were EPA to establish, for example, a default designation to Low-Priority. As a practical matter, however, EPA expects this situation to occur infrequently, based on its proposed criteria and considerations that will generally ensure that sufficient information is available to conduct a risk evaluation before initiating prioritization. Priority designations, whether they were based on sufficient information or a lack of sufficient information, are neither an



affirmation of risk nor safety. EPA therefore recognizes that all priority designations will need to be carefully communicated to the public.

For proposed designations as Low-Priority Substances, EPA is proposing to require that all comments that could be raised on the issues in the proposed designation must be presented during the comment period. Any issues not raised will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding. This is a well-established principle of administrative law and practice, *e.g.*, *Nuclear Energy Institute v. EPA*, 373 F.3d 1251, 1290–1291 (D.C. Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate here. EPA is restricting this to Low-Priority Substance designations, as it is the last opportunity for public input before EPA's action becomes final, and thus it is imperative that any issues are shared during this public comment period. By contrast, designation of a chemical substance as a High-Priority Substance is not final agency action. The statute mandates additional opportunities for public input during the risk evaluation process, and EPA does not consider it appropriate to restrict the public's ability to comment during these subsequent processes based on this early phase proceeding.

#### K. Final Priority Designation

After considering any additional information collected during the proposed designation step, as appropriate, the last step in the prioritization process is for EPA to finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance. The proposed rule specifies that EPA will publish the priority designation in the **Federal Register**, and will use the same docket. Again, TSCA prohibits costs or other non-risk factors from being considered in this designation. And, as with the proposed designation step, if information available to EPA remains insufficient to support the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation as a High-Priority Substance. Although final High-Priority designations based on insufficient information are unlikely for all the reasons described in Unit III.J., such a designation would require EPA to conduct a risk evaluation on that substance, and to support the risk evaluation with adequate information. EPA would need to develop or require development of the necessary

information and complete the risk evaluation within the 3-year statutory deadline.

#### L. Repopulation of High-Priority Substances

TSCA requires EPA to finalize a designation for at least one new High-Priority Substance upon completion of a risk evaluation for another chemical substance, other than a risk evaluation that was requested by a manufacturer. Because the timing for the completion of risk evaluation and/or the prioritization process will be difficult to predict, EPA intends to satisfy this 1-off-1-on replacement obligation as follows: In the notice published in the **Federal Register** finalizing the designation of a new High-Priority Substance, EPA will identify the complete or near-complete risk evaluation that the new High-Priority Substance will replace. So long as the designation occurs within a reasonable time before or after the completion of the risk evaluation, this will satisfy Congress' intent while avoiding unnecessary delay and the logistical challenges that would be associated with more perfectly aligning a High-Priority Substance designation with the completion of a risk evaluation.

#### M. Effect of Final Priority Designation

Final designation of a chemical substance as a High-Priority Substance requires EPA to immediately begin a risk evaluation on that chemical substance. It is important to note that High-Priority Substance designation does not mean that the Agency has determined that the chemical substance presents a risk to human health or the environment—only that the Agency intends to consider the chemical substance for further risk review and evaluation. A High-Priority Substance designation is not a final agency action and is not subject to judicial review or review under the Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*

Final designation of a chemical substance as a Low-Priority Substance means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation, if warranted. Notably, a Low-Priority Substance designation is explicitly subject to judicial review. 15 U.S.C. 2618(a)(1)(C).

#### N. Revision of Designation

TSCA provides that EPA may revise a final designation of a chemical substance from a Low-Priority Substance to a High-Priority Substance at any time based on information available to the Agency. The proposed

rule outlines the process the Agency will take to revise such a designation. Specifically, EPA would (1) re-screen the chemical substance incorporating the relevant information, (2) re-initiate the prioritization process and take public comment, (3) re-propose a priority designation and take public comment, and (4) re-finalize the priority designation. EPA will not revise a final designation of a chemical substance from High-Priority Substance to Low-Priority Substance, but rather see the risk evaluation process through to its conclusion.

#### IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014. Available online at: [https://www.epa.gov/sites/production/files/2015-01/documents/tsc\\_a\\_work\\_plan\\_chemicals\\_2014\\_update\\_final.pdf](https://www.epa.gov/sites/production/files/2015-01/documents/tsc_a_work_plan_chemicals_2014_update_final.pdf).
2. EPA. Framework for Metals Risk Assessment. EPA 120/R-07/001. March 2007. Available online at: <https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf>.
3. EPA. Science Policy Council Handbook: Risk Characterization. EPA/100/B-00/002. December 2000. Available online at: <https://www.epa.gov/risk/risk-characterization-handbook>.
4. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012. Available online at: [https://www.epa.gov/sites/production/files/2014-03/documents/work\\_plan\\_methods\\_document\\_web\\_final.pdf](https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf).
5. EPA. 2012 TSCA Work Plan Chemicals. June 2012. Available online at: [https://www.epa.gov/sites/production/files/2014-02/documents/work\\_plan\\_chemicals\\_web\\_final.pdf](https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf).
6. EPA. Safer Chemical Ingredients List (SCIL). Available online at: <https://www.epa.gov/saferchoice/safer-ingredients>. See also Master Criteria, September 2012, Version 2.1, available online at: [https://www.epa.gov/sites/production/files/2013-12/documents/dfe\\_master\\_criteria\\_safer\\_ingredients\\_v2\\_1.pdf](https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf).

#### V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be



found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

*B. Paperwork Reduction Act (PRA)*

This action does not contain any information collection activities that require approval under the PRA, 44 U.S.C. 3501 *et seq.* This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

*C. Regulatory Flexibility Act (RFA)*

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public, including small entities.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

*E. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This rulemaking addresses internal EPA operations and procedures and does not have any impact on human health or the environment.

**List of Subjects in 40 CFR Part 702**

Environmental protection, Chemicals, Chemical substances, Hazardous substances, Health and safety, Prioritization, Screening, Toxic substances.

Dated: December 27, 2016

**Gina McCarthy,**  
*Administrator.*

Therefore, 40 CFR chapter I, subchapter R, is proposed to be amended as follows:

**PART 702—[AMENDED]**

■ 1. The authority citation for part 702 is revised to read as follows:

**Authority:** 15 U.S.C. 2605 and 2619.

■ 2. Add subpart A to read as follows:

**PART 702—GENERAL PRACTICES AND PROCEDURES**

**Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation**

702.1 General Provisions.

702.3 Definitions.

702.5 Considerations for Potential Candidates for Prioritization.

702.7 Candidate Selection and Screening Review.

702.9 Initiation of Prioritization Process.

702.11 Proposed Priority Designation.

702.13 Final Priority Designation.

702.15 Revision of Designation.

702.17 Effect of Designation as a Low-Priority Substance.

702.19 Effect of Designation as a High-Priority Substance.

\* \* \* \* \*

**Authority:** 15 U.S.C. 2605 and 2619.

**Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation**

**§ 702.1 General Provisions.**

(a) *Purpose.* This regulation establishes the risk-based screening process for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b) of the Toxic Substances Control Act, as amended (15 U.S.C. 2605(b)).

(b) *Scope of designations.* EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of use of a chemical substance.

(c) *Categories of chemical substances.* Nothing in this subpart shall be interpreted as a limitation on EPA’s authority under 15 U.S.C. 2625(c) to take action, including the actions contemplated in this subpart, on a category of chemical substances.

(d) *Prioritization timeframe.* The Agency will publish a final priority designation for a chemical substance in no fewer than 9 months and no longer than 1 year following initiation of prioritization pursuant to 40 CFR 702.9.

(e) *Metals or metal compounds.* In identifying priorities for chemical

substances that are metals or metal compounds, EPA will, as appropriate, refer to relevant considerations from the Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum, dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(f) *Applicability.* These regulations do not apply to any chemical substance for which a manufacturer requests a risk evaluation under TSCA section 6(b)(4)(C) (15 U.S.C. 2605(b)(4)(C)).

### § 702.3 Definitions.

For purposes of this subpart, the following definitions apply:

*Act* means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*)

*EPA* means the U.S. Environmental Protection Agency.

*High-Priority Substance* means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

*Low-Priority Substance* means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

### § 702.5 Consideration of Potential Candidates for Prioritization.

(a) *Potential High-Priority Substance Candidates.* In identifying potential candidates for High-Priority Substances, EPA will generally consider whether information available to the Agency suggests there is hazard and exposure under a condition or conditions of use, and whether a risk evaluation would be needed to determine whether there is an unreasonable risk of injury to health or the environment.

(b) *Potential Low-Priority Substance Candidates.* In identifying potential candidates for Low-Priority Substances, EPA will generally consider whether information available to the EPA suggests such low hazard and/or exposure under all conditions of use that EPA is confident the chemical substances does not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed

or susceptible subpopulations identified as relevant by EPA, even in the absence of a risk evaluation.

### (c) *Exposure and Hazard Considerations for Potential Candidates.*

In identifying potential candidates for prioritization, EPA will generally evaluate whether or not the chemical substance meets one or more of the following exposure or hazard considerations:

- (1) Persistent, bioaccumulative, and toxic;
- (2) Used in children's products;
- (3) Used in consumer products;
- (4) Detected in human and/or ecological biomonitoring programs;
- (5) Potentially of concern for children's health;
- (6) High acute and chronic toxicity;
- (7) Probable or known carcinogen;
- (8) Neurotoxicity; or
- (9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency.

A chemical substance that meets one or more of these criteria will generally be considered as a potential candidate for further consideration as a High-Priority Substance. A chemical substance that meets none of these criteria will generally be considered as a potential candidate for further consideration as a Low-Priority Substance.

(d) *Available Information and Resources.* EPA expects it will often be difficult to timely require development of necessary chemical information, and receive, evaluate, and incorporate that information into analyses, during the prioritization and risk evaluation processes, within the statutory deadlines under the Act for prioritization and risk evaluation at 15 U.S.C. 2605 (b)(1)(C) and (b)(4)(G). Therefore, EPA will generally review and analyze the information necessary for both prioritization and risk evaluation prior to initiating the prioritization process for a chemical substance pursuant to 40 CFR 702.9. Specifically, in identifying potential candidates for prioritization, EPA expects to consider:

- (1) The availability of information and resources necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Administrator; and
- (2) The ability of EPA to timely develop or require development of information necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11; a risk evaluation pursuant to 40 CFR 702, subpart B; or

other such action as determined by the Agency.

(e) *Insufficient Information.* In the absence of sufficient information to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA may use its authorities under the Act, and other information gathering authorities, to gather or require the generation of the needed information on a chemical substance before initiating the prioritization process for that chemical substance.

### § 702.7 Candidate Selection and Screening Review.

(a) *Preferences and TSCA Work Plan.*

In selecting a candidate for prioritization as a High-Priority Substance, EPA will:

- (1) Give preference to:
  - (A) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3, and
  - (B) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High-Priority Substance or Low-Priority Substance pursuant to 40 CFR 702.13.

(b) *General Objective.* In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering available information on the relative hazard and exposure of potential candidates. EPA may also consider the relative hazard and exposure of a potential candidate's substitutes. EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order.

(c) *Screening Review.* Following selection of a candidate chemical substance, EPA will generally use available information to screen the candidate chemical substance against the following criteria and considerations:

- (1) The chemical substance's hazard and exposure potential;

(2) The chemical substance's persistence and bioaccumulation;  
 (3) Potentially exposed or susceptible subpopulations;

(4) Storage of the chemical substance near significant sources of drinking water;

(5) The chemical substance's conditions of use or significant changes in conditions of use;

(6) The chemical substance's production volume or significant changes in production volume; and

(7) Any other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion.

(d) *Information sources.* In conducting the screening review in paragraph (c) of this section, EPA expects to consider sources of information relevant to the listed criteria, including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

(e) The purpose of the preferences and criteria in paragraph (a) of this section and the screening review in paragraph (c) of this section are to inform EPA's decision whether or not to initiate the prioritization process pursuant to 40 CFR 702.9, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to 40 CFR 702.11.

(f) If, after the screening review in paragraph (c) of this section, EPA believes it will not have sufficient information to support a proposed priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA is likely to use its authorities under the Act, and other information gathering authorities, to generate the needed information before initiating prioritization pursuant to 40 CFR 702.9.

#### **§ 702.9 Initiation of Prioritization Process.**

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that all or most of the information necessary to prioritize and perform a risk evaluation on the substance already exists.

(b) EPA will initiate prioritization by publishing a notice in the **Federal Register** identifying a chemical substance for prioritization and the results of the screening review conducted pursuant to 40 CFR 702.7(c).

(c) The prioritization timeframe in 40 CFR 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) The results of the screening review published pursuant to paragraph (b) of this section will identify, in a form and manner that EPA deems appropriate, the information analysis and basis used in conducting the screening process. Subject to 15 U.S.C. 2613, copies of the information will also be placed in a public docket established for each chemical substance.

(e) Publication of a notice in the **Federal Register** pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information regarding the results of the screening review conducted pursuant to 40 CFR 702.7(c), and any additional information on the chemical substance that pertains to the criteria and considerations at 40 CFR 702.7(c).

(f) EPA may, in its discretion, extend the public comment period in paragraph (b) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B).

#### **§ 702.11 Proposed Priority Designation.**

(a) Based on the results of the screening review in 40 CFR 702.7(c), relevant information received from the public as described in 40 CFR 702.9(e), and other information as appropriate and in EPA's discretion, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a proposed priority designation.

(c) If information available to EPA remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period pursuant to 40 CFR 702.9(f), EPA will propose to designate the chemical substance as a High-Priority Substance.

(d) EPA may propose to designate a chemical substance as a High-Priority Substance based on the proposed conclusion that the chemical substance satisfies the definition of High-Priority Substance in 40 CFR 702.3 under any one or more uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602. EPA will propose to designate a chemical substance as a Low-Priority Substance

based only on the proposed conclusion that the chemical substance satisfies the definition of Low-Priority Substance in 40 CFR 702.3 under all uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602.

(e) EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a comment period of 90 days, during which time the public may submit comment on EPA's proposed designation. EPA will open a docket to facilitate receipt of public comment.

(f) For chemical substances that EPA proposes to designate as Low-Priority Substances, EPA will specify in the notice published pursuant to paragraph (e) of this section that all comments that could be raised on the issues in the proposed designation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

#### **§ 702.13 Final Priority Designation.**

(a) After considering any additional information collected from the proposed designation process in 40 CFR 702.11, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a final priority designation.

(c) EPA will publish each final priority designation in the **Federal Register**.

(d) EPA will finalize a designation for at least one High-Priority Substance for each risk evaluation it completes, other than a risk evaluation that was requested by a manufacturer pursuant to 40 CFR 702, subpart B. The obligation in 15 U.S.C. 2605(b)(3)(C) will be satisfied by the designation of at least one High-Priority Substance where such designation specifies the risk evaluation that the designation corresponds to, and where the designation occurs within a reasonable time before or after the completion of the risk evaluation.

(e) If information available to EPA remains insufficient to enable the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation of the chemical substance as a High-Priority Substance.

**§ 702.15 Revision of Designation.**

EPA may revise a final designation of chemical substance from Low-Priority to High-Priority Substance at any time based on information available to the Agency. To revise such a designation, EPA will re-screen the chemical substance pursuant to 40 CFR 702.7(c), re-initiate the prioritization process on that chemical substance in accordance with 40 CFR 702.9, propose a priority designation pursuant to 40 CFR 702.11, and finalize the priority designation pursuant to 40 CFR 702.13. EPA will not revise a final designation of a chemical substance from a High-Priority Substance designation to Low-Priority.

**§ 702.17 Effect of Designation as a Low-Priority Substance.**

Designation of a chemical substance as a Low-Priority Substance under 40 CFR 702.3 means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation pursuant to 40 CFR 702.15, if warranted.

**§ 702.19 Effect of Designation as a High-Priority Substance.**

Final designation of a chemical substance as a High-Priority Substance under 40 CFR 702.13 initiates a risk evaluation pursuant to 40 CFR 702, subpart B. Designation as a High-Priority Substance is not a final agency

action and is not subject to judicial review.

\* \* \* \* \*  
[FR Doc. 2017-00051 Filed 1-13-17; 8:45 am]  
**BILLING CODE 6560-50-P**

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Part 64**

[CG Docket No. 02-278; Report No. 3066]

**Petition for Reconsideration of Action in Rulemaking Proceeding**

**AGENCY:** Federal Communications Commission.

**ACTION:** Petition for reconsideration.

**SUMMARY:** A Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding, Sarah E. Ducich and Mark W. Brennan on behalf of Navient Corp., Joseph Popevis and Rich Benenson on behalf of Nelnet Servicing LLC, Rebecca Emily Rapp on behalf of Great Lakes Higher Education Corporation, Jason L. Swartley on behalf of Pennsylvania Higher Education Assistance Agency, and Winfield P. Crigler on behalf of Student Loan Servicing Alliance.

**DATES:** Oppositions to the Petition must be filed on or before February 1, 2017. Replies to an opposition must be filed on or before February 13, 2017.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:**

Kristi Thornton, Consumer Policy Division, Consumer and Governmental Affairs Bureau, at (202) 418-2467 or email: *Kristi.Thornton@fcc.gov*.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's document, Report No. 3066, released January 6, 2017. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY-A257, Washington, DC 20554. It also may be accessed online via the Commission's Electronic Comment Filing System at: <https://www.fcc.gov/ecfs/filing/1217190700960/document/1217190700960fd71>. The Commission will not send a copy of this document pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this document does not have an impact on any rules of particular applicability.

*Subject:* In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, FCC 16-99, published at 81 FR 80594, November 16, 2016, in CG Docket No. 02-278. This document is being published pursuant to 47 CFR 1.429(e). See also 47 CFR 1.4(b)(1) and 1.429(f), (g).

*Number of Petitions Filed:* 1.

Federal Communications Commission.

**Marlene H. Dortch,**  
*Secretary.*

[FR Doc. 2017-00848 Filed 1-13-17; 8:45 am]  
**BILLING CODE 6712-01-P**

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Rural Utilities Service

#### Announcement of Application Deadlines and Requirements for Section 313A Guarantees for Bonds and Notes Issued for Electrification or Telephone Purposes Loan Program for Fiscal Year (FY) 2017

**AGENCY:** Rural Utilities Service, USDA.

**ACTION:** Notice of Solicitation of Applications (NOSA).

**SUMMARY:** The Rural Utilities Service (RUS), an agency of the United States Department of Agriculture (USDA), announces the application window, requirements and funding for loans that may become available for Fiscal Year (FY) 2017 under the Guarantees for Bonds and Notes Issued for Electrification or Telephone Purposes Program (the 313A Program) authorized under the Rural Electrification Act of 1936, as amended, and related terms. Under the 313A Program, the Federal Financing Bank (FFB) will make loans to the selected applicant(s) and RUS will guarantee the applicant(s)'s repayment of the loans to FFB. Selected applicants may use the proceeds of loan funds made available under the 313A Program to make loans to borrowers for electrification or telecommunications purposes, or to refinance bonds or notes previously issued by applicants for such purposes. The proceeds of the guaranteed bonds and notes are not to be used by applicants to directly or indirectly fund projects for the generation of electricity.

This notice is based on loan levels contemplated by the FY 17 Continuing Resolution and on information available to the agency at the time of this notice. The final amount of funding made available under this notice could be affected by subsequent Congressional action or subsidy rate calculations. Last year, the RUS obligated \$750 million in

loan funds for this program. It is necessary to publish this notice at this time to ensure that applicants have sufficient time to prepare applications and to ensure that the agency has sufficient time and resources to evaluate applications.

**DATES:** Completed applications must be received by RUS no later than 5:00 p.m. Eastern Daylight Time (EDT) on April 28, 2017.

**ADDRESSES:** Applicants are required to submit one original and two copies of their loan applications to the U.S. Department of Agriculture, Rural Utilities Service, Electric Program, ATTN: Amy McWilliams, Management Analyst, 1400 Independence Avenue SW., STOP 1568, Room 0226-S, Washington, DC 20250-1568.

**FOR FURTHER INFORMATION CONTACT:** For further information contact Amy McWilliams, Management Analyst, 1400 Independence Avenue SW., STOP 1568, Room 0226-S, Washington, DC 20250-1568. Telephone: (202) 205-8663; or email: [amy.mcwilliams@wdc.usda.gov](mailto:amy.mcwilliams@wdc.usda.gov)

#### SUPPLEMENTARY INFORMATION:

##### Overview

*Federal Agency:* Rural Utilities Service, USDA.

*Funding Opportunity Title:* Guarantees for Bonds and Notes Issued for Electrification or Telephone Purposes for Fiscal Year (FY) 2017.

*Announcement Type:* Guarantees for Bonds and Notes.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 10.850

*Due Date for Applications:* Applications must be received by RUS by 5:00 p.m. Eastern Daylight Time (EDT) on April 28, 2017.

#### Items in Supplementary Information

- I. Funding Opportunity Description
- II. Award Information
- III. Eligibility Information
- IV. Fiscal Year 2017 Application and Submission Information
- V. Application Review Information
- VI. Issuance of the Guarantee
- VII. Guarantee Agreement
- VIII. Reporting Requirements
- IX. Award Administration Information
- X. National Environmental Policy Act Certification
- XI. Other Information and Requirements
- XII. Agency Contacts: Web site, Phone, Fax, Email, Contact Name
- XIII. Non-Discrimination Statement: USDA Non-Discrimination Statement, How To

File a Complaint, Persons With Disabilities

## I. Funding Opportunity Description

### A. Purpose of the 313A Program

The purpose of the 313A Program is to make guaranteed loans to selected applicants (each referred to as "Guaranteed Lender" in this NOSA and in the Program Regulations) that are to be used (i) to make loans for electrification or telecommunications purposes eligible for assistance under the RE Act (defined herein) and regulations for the 313A Program located at 7 CFR part 1720 (also referred to as the "Program Regulations" in this NOSA), or (ii) to refinance bonds or notes previously issued by the Guaranteed Lender for such purposes. The proceeds of the guaranteed bonds and notes are not to be used by the Guaranteed Lender to directly or indirectly fund projects for the generation of electricity.

### B. Statutory Authority

The 313A Program is authorized by Section 313A of the Rural Electrification Act of 1936, as amended (7 U.S.C. 940c-1) (the RE Act) and is implemented by regulations located at 7 CFR part 1720. The Administrator of RUS (the Administrator) has been delegated responsibility for administering the 313A Program.

### C. Definition of Terms

The definitions applicable to this NOSA are published at 7 CFR 1720.3.

### D. Application Awards

RUS will review and evaluate applications received in response to this NOSA based on the regulations at 7 CFR 1720.7, and as provided in this NOSA.

## II. Award Information

*Type of Awards:* Guaranteed Loans.  
*Fiscal Year Funds:* FY 2017.

*Award Amounts:* RUS anticipates making multiple approvals under this NOSA. The number, amount and terms of awards under this NOSA will depend, in part, on the number of eligible applications and the amount of funds requested. In determining whether or not to make an award, the RUS will take overall program policy objectives into account.

*Application Date:* See **SUPPLEMENTARY INFORMATION** herein.

*Award Date:* Awards will be made on or before September 29, 2017.

*Preferred Schedule of Loan Repayment:* Amortization Method (level debt service).

### III. Eligibility Information

#### A. Eligible Applicants

1. *To be eligible to participate in the 313A Program, a Guaranteed Lender must be:*

a. A bank or other lending institution organized as a private, not-for-profit cooperative association, or otherwise organized on a non-profit basis; and

b. Able to demonstrate to the Administrator that it possesses the appropriate expertise, experience, and qualifications to make loans for electrification or telephone purposes.

2. *To be eligible to receive a guarantee, a Guaranteed Lender's bond must meet the following criteria:*

a. The Guaranteed Lender must furnish the Administrator with a certified list of the principal balances of eligible loans outstanding and certify that such aggregate balance is at least equal to the sum of the proposed principal amount of guaranteed bonds to be issued, including any previously issued guaranteed bonds outstanding;

b. The guaranteed bonds to be issued by the Guaranteed Lender would receive an underlying investment grade rating from a Rating Agency, without regard to the guarantee; and

3. A lending institution's status as an eligible applicant does not assure that the Administrator will issue the guarantee sought in the amount or under the terms requested, or otherwise preclude the Administrator from declining to issue a guarantee.

#### B. Other Eligibility Requirements

Applications will only be accepted from lenders that serve rural areas defined in 7 CFR 1710.2(a) as (i) Any area of the United States, its territories and insular possessions (including any area within the Federated States of Micronesia, the Marshall Islands, and the Republic of Palau) other than a city, town, or unincorporated area that has a population of greater than 20,000 inhabitants; and (ii) Any area within a service area of a borrower for which a borrower has an outstanding loan as of June 18, 2008, made under titles I through V of the Rural Electrification Act of 1936 (7 U.S.C. 901–950bb). For initial loans to a borrower made after June 18, 2008, the "rural" character of an area is determined at the time of the initial loan to furnish or improve service in the area.

### IV. Fiscal Year 2017 Application and Submission Information

#### A. Applications

All applications must be prepared and submitted in accordance with this NOSA and 7 CFR 1720.6 (Application Process). To ensure the proper preparation of applications, applicants should carefully read this NOSA and 7 CFR part 1720 (available online at <http://www.ecfr.gov/cgi-bin/text-id.x?SID=9295e45c9a0f6a857d800fbc5d4e2fb&mc=true&node=pt7.11.1720&rgn=div5>).

#### B. Content and Form of Submission

In addition to the required application specified in 7 CFR 1720.6, all applicants must submit the following additional required documents and materials:

1. *Form AD-1047, Certification Regarding Debarment, Suspension and Other Responsibility Matters Primary Covered Transactions.* This form contains certain certifications relating to debarment and suspension, convictions, criminal charges, and the termination of public transactions (See 2 CFR part 417, and 7 CFR 1710.123). This form is available at <http://www.ocio.usda.gov/policy-directives-records-forms/forms-management/approved-computer-generated-forms>;

2. *Restrictions on Lobbying.* Applicants must comply with the requirements with respect to restrictions on lobbying activities. (See 2 CFR part 418, and 7 CFR 1710.125). This form is available at <http://www.rd.usda.gov/publications/regulations-guidelines/electric-sample-documents>;

3. *Uniform Relocation Act assurance statement.* Applicants must comply with 49 CFR part 24, which implements the Uniform Relocation Assistance and Real Property Acquisition Policy Act of 1970, as amended. (See 7 CFR 1710.124). This form is available at <http://www.rd.usda.gov/publications/regulations-guidelines/electric-sample-documents>;

4. *Federal debt delinquency requirements.* This report indicates whether or not the applicants are delinquent on any Federal debt (See 7 CFR 1710.126 and 7 CFR 1710.501(a)(13)). This form is available at <http://www.rd.usda.gov/publications/regulations-guidelines/electric-sample-documents>;

5. *RUS Form 266, Compliance Assurance.* Applicants must submit a non-discrimination assurance commitment to comply with certain regulations on non-discrimination in program services and benefits and on equal employment opportunity as set forth in 7 CFR parts 15 and 15b and 45

CFR part 90. This form is available at <http://www.rd.usda.gov/publications/regulations-guidelines/forms-publications>;

6. *Articles of incorporation and bylaws:* See 7 CFR 1710.501(a)(14). These are required if either document has been amended since the last loan application was submitted to RUS, or if this is the applicant's first application for a loan under the RE Act; and

7. *Form AD 3030, Representations Regarding Felony Conviction and Tax Delinquency Status for Corporation Applications.* Applicants are required to complete this form if they are a corporation. This form is available at <http://www.ocio.usda.gov/policy-directives-records-forms/forms-management/approved-computer-generated-forms>.

#### C. Supplemental Documents for Submission

1. *Cash flow projections and assumptions:* Each applicant must include five-year pro-forma cash flow projections or business plans and clearly state the assumptions that underlie the projections, demonstrating that there is reasonable assurance that the applicant will be able to repay the guaranteed loan in accordance with its terms (See 7 CFR 1720.6(4)).

2. *Pending litigation statement:* A statement from the applicant's counsel listing any pending litigation, including levels of related insurance coverage and the potential effect on the applicant.

### V. Application Review Information

#### A. Application Evaluation

1. *Administrator Review.* Each application will be reviewed by the Administrator to determine whether it is eligible under 7 CFR 1720.5, the information required under 7 CFR 1720.6 is complete, and the proposed guaranteed bond complies with applicable statutes and regulations. The Administrator can at any time reject an application that fails to meet these requirements.

a. Applications will be subject to a substantive review, on a competitive basis, by the Administrator based upon the evaluation factors listed in 7 CFR 1720.7(b).

2. *Decisions by the Administrator.* The Administrator will approve or deny applications in a timely manner as such applications are received; provided, however, that in order to facilitate competitive evaluation of applications, the Administrator may from time to time defer a decision until more than one application is pending. The Administrator may limit the number of

guarantees made to a maximum of five per year, to ensure a sufficient examination is conducted of applicant requests. RUS will notify the applicant in writing of the Administrator's approval or denial of an application. Approvals for guarantees will be conditioned upon compliance with 7 CFR 1720.4 and 7 CFR 1720.6. The Administrator reserves the discretion to approve an application for an amount less than that requested.

#### B. Independent Assessment

Before a guarantee decision is made by the Administrator, the Administrator shall request that FFB review the rating agency determination required by 7 CFR 1720.5(b)(2) as to whether the bond or note to be issued would be below investment grade without regard to the guarantee.

#### VI. Issuance of the Guarantee

The requirements under this section must be met by the applicant prior to the endorsement of a guarantee by the Administrator (See 7 CFR 1720.8).

#### VII. Guarantee Agreement

Each Guaranteed Lender will be required to enter into a Guarantee Agreement with RUS that contains the provisions described in 7 CFR 1720.8 (Issuance of the Guarantee), 7 CFR 1720.9 (Guarantee Agreement), and 7 CFR 1720.12 (Reporting Requirements). The Guarantee Agreement will also obligate the Guaranteed Lender to pay, on a semi-annual basis, a guarantee fee equal to 15 basis points (0.15 percent) of the outstanding principal amount of the guaranteed loan (See 7 CFR 1720.10).

#### VIII. Reporting Requirements

Guaranteed Lenders are required to comply with the financial reporting requirements and pledged collateral review and certification requirements set forth in 7 CFR 1720.12.

#### IX. Award Administration Information

##### Award Notices

RUS will send a commitment letter to an applicant once the loan is approved. Applicants must accept and commit to all terms and conditions of the loan which are requested by RUS and FFB as follows:

1. *Compliance conditions.* In addition to the standard conditions placed on the section 313A Program or conditions requested by the Agency to ensure loan security and statutory compliance, applicants must comply with the following conditions:

a. Each Guaranteed Lender selected under the 313A Program will be

required to post collateral for the benefit of RUS in an amount equal to the aggregate amount of loan advances made to the Guaranteed Lender under the 313A Program.

b. The pledged collateral shall consist of outstanding notes or bonds payable to the Guaranteed Lender (the Eligible Securities) and shall be placed on deposit with a collateral agent for the benefit of RUS. To be deemed Eligible Securities that can be pledged as collateral, the notes or bonds to be pledged (i) cannot be classified as non-performing, impaired, or restructured under generally accepted accounting principles, (ii) cannot be comprised of more than 30% of bonds or notes from generation and transmission borrowers or (iii) cannot have more than 5% of notes and bonds be from any one particular borrower.

c. The Guaranteed Lender will be required to place a lien on the pledged collateral in favor of RUS (as secured party) at the time that the pledged collateral is deposited with the collateral agent. RUS will have the right, in its sole discretion, within 14 business days to reject and require the substitution of any Pledged Collateral that the Guaranteed Lender deposits as collateral with the collateral agent. Prior to receiving any advances under the 313A Program, the Guaranteed Lender will be required to enter into a pledge agreement, satisfactory to RUS, with a banking institution serving as collateral agent.

d. The Guaranteed Lender will be required to maintain pledged collateral at a level that is sufficient to ensure that, upon the occurrence of an event of default, resources will be available to cover (i) principal, interest, fees and (ii) reasonable expenses incurred by RUS as a result of a default or incurred pursuant to RUS's obligation to make related payments to FFB under the RUS Guarantee on all guarantees issued by RUS to FFB for the benefit of the Guaranteed Lender under Section 313A of the RE Act. The Guaranteed Lender will also be required to agree that the pledged collateral can be used for such purposes.

e. The Guaranteed Lender will be required to agree to not to take any action that would have the effect of reducing the value of the Pledged Collateral below the level described above.

f. Applicants must certify to the RUS, the portion of their Eligible Loan portfolio that is:

- (1) Refinanced RUS debt;
- (2) Debt of borrowers for whom both

RUS and the applicants have outstanding loans; and

(3) Debt of borrowers for whom both RUS and the applicant have outstanding concurrent loans pursuant to Section 307 of the RE Act, and the amount of Eligible Loans.

#### 2. Compliance with Federal Laws.

Applicants must comply with all applicable Federal laws and regulations.

a. This obligation is subject to the provisions contained in the Consolidated Appropriations Act, 2016, Public Law 114-113, Division A, Title VII, Sections 745 and 746, as amended and/or subsequently enacted for USDA agencies and offices regarding corporate felony convictions and corporate federal tax delinquencies.

b. An authorized official within your organization must execute, date, and return the loan commitment letter and the Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants (Form AD-3031) to RUS by September 28, 2017; otherwise, the commitment will be void. This form is available at <http://www.ocio.usda.gov/policy-directives-records-forms/forms-management/approved-computer-generated-forms>.

c. Uniform Commercial Code (UCC) Filing. The Borrower must provide RUS with evidence that the Borrower has filed the UCC financing statement required pursuant to Section 2.05(i) of the Pledge Agreement. Upon filing of the appropriate UCC financing statement, the Guaranteed Lender will provide RUS with a perfection opinion by outside counsel, satisfactory to RUS, which demonstrates that RUS's security interest in the Pledged Collateral under the Pledge Agreement is perfected.

d. Additional conditions may be instituted for future obligations.

#### X. National Environmental Policy Act Certification

For any proceeds to be used to refinance bonds and notes previously issued by the Guaranteed Lender for the RE Act purposes that are not obligated with specific projects, RUS has determined that these financial actions will not individually or cumulatively have a significant effect on the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR parts 1500-1508. However, for any new projects funded under the 313A Program, applicants must consult with RUS and comply with the Agency regulations at 7 CFR part 1970.

#### XI. Other Information and Requirements

Applications must contain all of the required elements of this NOSA and all



standard requirements as required by 7 CFR part 1720. Additional supporting data or documents may be required by RUS depending on the individual application or financial conditions. All applicants must comply with all Federal Laws and Regulations.

## XII. Agency Contacts

A. *Web site:* <http://www.rd.usda.gov/programs-services/all-programs/electric-programs>

B. *Phone:* (202) 205-8663.

C. *Fax:* (844) 749-0736.

D. *Email:* [amy.mcwilliams@wdc.usda.gov](mailto:amy.mcwilliams@wdc.usda.gov)

E. *Main point of contact:* Amy McWilliams, Management Analyst, 1400 Independence Avenue SW., STOP 1568, Room 0226-S, Washington, DC 20250-1568.

## XIII. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.*, Braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027. This form is available at <http://www.ocio.usda.gov/policy-directives-records-forms/forms-management/approved-computer-generated-forms> and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992.

Submit your completed form or letter to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410;

(2) *Fax:* (202) 690-7442; or

(3) *Email:* [program.intake@usda.gov](mailto:program.intake@usda.gov).

USDA is an equal opportunity provider, employer, and lender.

**Authority:** 7 U.S.C. 940c-1.

Dated: December 20, 2016.

**Joshua Cohen,**

*Deputy Administrator, Rural Utilities Service.*

[FR Doc. 2017-00831 Filed 1-13-17; 8:45 am]

**BILLING CODE 3410-15-P**

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Delaware Advisory Committee; Correction

**AGENCY:** Commission on Civil Rights.

**ACTION:** Notice; revision.

**SUMMARY:** The Commission on Civil Rights published a notice in the **Federal Register** of September 15, 2016, concerning a meeting of the Delaware Advisory Committee. The meeting time for the January 18, 2017 is changed.

**FOR FURTHER INFORMATION CONTACT:** Ivy Davis, (202) 376-7533.

### Revision

In the **Federal Register** of Delaware, in FR Doc. 2016-22196, on page 63468, revise the first paragraph to read:

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the time of the January 18, 2017 planning meeting of the Delaware State Advisory Committee to the Commission is changed to 10:00 a.m. EST.

Dated: January 10, 2017.

**David Mussatt,**

*Supervisory Chief, Regional Programs Coordination Unit.*

[FR Doc. 2017-00768 Filed 1-13-17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

[B-5-2017]

### Foreign-Trade Zone 124—Gramercy, Louisiana, Application for Reorganization, (Expansion of Service Area) Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of South Louisiana, grantee of Foreign-Trade Zone 124, requesting authority to reorganize the zone to expand its service area under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR Sec. 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on January 10, 2017.

FTZ 124 was approved by the FTZ Board on December 20, 1985 (Board Order 319, 50 FR 53351, December 31, 1985), reorganized under the ASF on January 31, 2012 (Board Order 1814, 77 FR 6059, February 7, 2012), and its service area was expanded on July 16, 2013 (Board Order 1908, 78 FR 44094-44095, July 23, 2013). The zone currently has a service area that includes St. Charles, St. John the Baptist, St. James, Lafourche, St. Mary and Tangipahoa Parishes, Louisiana.

The applicant is now requesting authority to expand the service area of the zone to include Plaquemines and Assumption Parishes, Louisiana, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Gramercy Customs and Border Protection Port of Entry.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be



addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is March 20, 2017. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 3, 2017.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via [www.trade.gov/ftz](http://www.trade.gov/ftz). For further information, contact Camille Evans at [Camille.Evans@trade.gov](mailto:Camille.Evans@trade.gov) or (202) 482-2350.

Dated: January 10, 2017.

**Andrew McGilvray,**  
*Executive Secretary.*

[FR Doc. 2017-00870 Filed 1-13-17; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

[B-04-2017]

#### **Foreign-Trade Zone (FTZ) 277— Western Maricopa County, Arizona Notification of Proposed Production Activity; IRIS USA, Inc. (Plastic Household Storage/Organizational Containers), Surprise, Arizona**

IRIS USA, Inc. (IRIS) submitted a notification of proposed production activity to the FTZ Board for its facility in Surprise, Arizona, within FTZ 277. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on December 23, 2016.

IRIS has a pending production notification to produce plastic household storage/organizational containers and pet carriers/pens within Site 12 of FTZ 277 (B-68-2016, 81 FR 71045-71046, October 14, 2016). The current request would add a foreign-status component (steel wire dividers) to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status component described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt IRIS from customs duty payments on the foreign-status component used in export production. On its domestic sales, IRIS would be

able to choose the duty rates during customs entry procedures that apply to finished products—plastic household storage/organizational containers and pet carriers/pens (duty rates range from free to 5.3%)—authorized by the FTZ Board for the foreign-status steel wire dividers (duty rate, 3.4%). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is February 27, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via [www.trade.gov/ftz](http://www.trade.gov/ftz).

For further information, contact Diane Finver at [Diane.Finver@trade.gov](mailto:Diane.Finver@trade.gov) or (202) 482-1367.

Dated: January 9, 2017.

**Andrew McGilvray,**  
*Executive Secretary.*

[FR Doc. 2017-00867 Filed 1-13-17; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### **Submission for OMB Review; Comment Request; Voluntary Self- Disclosure of Antiboycott Violations**

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* Bureau of Industry and Security.

*Title:* Voluntary Self-Disclosure of Antiboycott Violations.

*Form Number(s):* N/A.

*OMB Control Number:* 0694-0132.

*Type of Review:* Regular submission.

*Estimated Total Annual Burden*

*Hours:* 7,230.

*Estimated Number of Respondents:* 15.

*Estimated Time per Response:* 10 to 600 hours.

*Needs and Uses:* This collection of information supports enforcement of the Antiboycott provisions of the Export Administration Regulations (EAR) by providing a method for industry to

voluntarily self-disclose Antiboycott violations.

*Affected Public:* Business or other for-profit organizations.

*Frequency:* On Occasion.

*Respondent's Obligation:* Voluntary.

This information collection request may be viewed at [reginfo.gov](http://reginfo.gov) <http://www.reginfo.gov/public/>. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to (202) 395-5806.

**Sheleen Dumas,**

*PRA Departmental Lead, Office of the Chief Information Officer.*

[FR Doc. 2017-00798 Filed 1-13-17; 8:45 am]

BILLING CODE 3510-33-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### Order Relating To Berty Tyloo

In the Matter of: Berty Tyloo with last known addresses of: Rue du Pont Nerf 2, Morges, Switzerland and Rue du Centre, 2, 1131 Tolochenaz, Morges, Switzerland, Respondent

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS"), has notified Berty Tyloo, of Morges, Switzerland ("Tyloo"), of its intention to initiate an administrative proceeding against Tyloo pursuant to Section 766.3 of the Export Administration Regulations (the "Regulations"),<sup>1</sup> and Section 13(c) of the Export Administration Act of 1979, as amended (the "Act"),<sup>2</sup> through the issuance of a Proposed Charging Letter to Tyloo that alleges that Tyloo committed one violation of the Regulations. Specifically, the charge is:

<sup>1</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730-774 (2016). The charged violation occurred in 2013. The Regulations governing the violation at issue are found in the 2013 version of the Code of Federal Regulations (15 CFR parts 730-774). The 2016 Regulations set forth the procedures that apply to this matter.

<sup>2</sup> 50 U.S.C. 4601-4623 (Supp. III 2015). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 4, 2016 (81 FR 52,587 (Aug. 8, 2016)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2012)).

**Charge 1 15 CFR 764.2(g):  
Misrepresentation and Concealment of  
Facts in the Course of an Investigation**

On or about June 14, 2013, Tyloo made false or misleading statements to BIS in the course of an investigation. Specifically, Tyloo was interviewed by two BIS supervisory special agents on or about June 14, 2013, in relation to an investigation of unlicensed exports and reexports to Syria of items subject to the Regulations and manufactured by Agilent Technologies, Inc. (“Agilent”), a U.S. company. As early as 2001, Tyloo was the area sales manager or distribution channel manager for the Middle East and Africa for Agilent products for European subsidiaries or affiliates of Agilent, including with regard to the sale and distribution of Agilent products to Syria through a Lebanese distributor or reseller, Technoline SAL (“Technoline”).<sup>3</sup> In addition, upon information and belief, Tyloo had an ownership interest in Technoline from at least March 2003 until at least the spring of 2008, as demonstrated, *inter alia*, by correspondence between Tyloo and Technoline management or ownership during this time period in which Tyloo sought information regarding his “share” and “assets” and “profit” in or from Technoline.

During the June 2013 interview, Tyloo stated that he had “no idea” how Agilent products had ended up in Syria and that, as far as he knew, all such products had stayed in Lebanon. Similarly, when asked if Technoline had ever shipped U.S.-origin items to Syria, Tyloo stated, “No, not to my knowledge.” At the time he made these statements, Tyloo knew they were false or misleading and that, in fact, Technoline had sold and distributed Agilent items to Syria beginning in at least 2004. Between at least November 2004 and December 2010, Technoline served as a distributor/reseller of Agilent products to several countries in the Middle East region pursuant to an International Designated Reseller Program Agreement (“reseller agreement”) entered into annually with Agilent’s Swiss affiliates.<sup>4</sup> Each of these

reseller agreements explicitly stated that Technoline’s territory included Syria. Moreover, on or about January 1, 2010, Tyloo electronically signed the 2010 version of the reseller agreement on Agilent Switzerland’s behalf. Nonetheless, during the June 2013 interview, Tyloo falsely or misleadingly omitted any mention of Syria in describing the countries in Technoline’s territory under the reseller agreements.

Tyloo’s role as the area sales manager or distribution channel manager for Agilent products in the Middle East provided Tyloo access to information about Technoline’s sale and distribution of Agilent products to Syria. Upon information and belief, his ownership stake in Technoline also provided him with access to such information. In addition, consistent with the longstanding reseller arrangement described above, on various occasions Tyloo acknowledged Technoline’s Syria business involving Agilent products. For example, in a November 14, 2004 message captioned “Agilent sales in Technoline,” Tyloo informed two Technoline officials that he “kept on Syria” in a “contract” for Fiscal Year 2005 between Technoline and Agilent, noting further that even if the Agilent contract administrator removed the reference, “THIS SHOULD NOT STOP US SELLING THERE (capitalization in the original).”<sup>5</sup> On or about March 31, 2009, Tyloo thanked Technoline’s area sales manager for his “continuous support and all the orders that you [and] your team delivers every month,” citing “your tough territories like Lebanon, Syria, Iraq . . . .” Additionally, on or about November 23, 2009, Technoline’s area sales manager provided Tyloo with business plans for several countries in

Technologies Europe B.V. Technoline signed the 2008–2010 versions of the reseller agreement with Agilent Technologies International SARL. See also note 3, *supra*.

<sup>5</sup> In May 2004, six months prior to Tyloo’s November 14, 2004 message, the U.S. Government implemented restrictions on the export and reexport to Syria of U.S.-origin items (with the exception of food and certain medicines). General Order No. 2 of May 14, 2004, Supp. No. 1 to part 736 to the Regulations, was issued pursuant to the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003, enacted on December 12, 2003, and Executive Order 13338 of May 11, 2004. In December 2011, the controls on exports and reexports to Syria were moved from General Order No. 2 to Section 746.9 of the Regulations. The licensing requirements continued unchanged. See 76 FR 77,115 (Dec. 12, 2011). During the June 2013 interview, Tyloo admitted that he had received regular training on U.S. export controls from Agilent’s legal department during his tenure with the Agilent subsidiaries or affiliates, including regarding embargoed and sanctioned destinations, and that he knew that U.S.-origin items could not be shipped to, *inter alia*, Syria. Tyloo also stated that he had received annual export controls training while he was employed by HP.

the Middle East, including Syria, and noted in the accompanying message that the “main focus” for 2010 would include “Pharma[ceuticals] in Syria” and “Mid Range products in Academia (Syria and Iraq).” (Parenthetical in original). Tyloo requested these business plans in preparation for his upcoming performance evaluations at Agilent Switzerland. Similarly, in December 2010, Tyloo gave a presentation at a meeting in Spain involving multiple Agilent European affiliates, in which he highlighted sales of Agilent products to Syria.

As alleged herein, Tyloo made false or misleading statements to BIS in the course of an investigation, in violation of Section 764.2(g) of the Regulations. Tyloo did so even though he acknowledged during the June 2013 interview that providing false or misleading information to the BIS agents was unlawful.

*Whereas*, BIS and Tyloo have entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations, whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein; and

*Whereas*, I have approved of the terms of such Settlement Agreement; *it is therefore ordered*:

*First*, for a period of three (3) years from the date of this Order, Berty Tyloo, with last known addresses of Rue du Pont Nef 2, Morges, Switzerland, and Rue du Centre, 2, 1131 Tolochenaz, Morges, Switzerland, and when acting for or on his behalf, his successors, assigns, representatives, agents, or employees (hereinafter collectively referred to as “Denied Person”), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as “item”) exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States

<sup>3</sup> From in or about November 1999, until in or about May 2011, Tyloo was employed first by Agilent Technologies Europe B.V. and then Agilent Technologies International SARL. Tyloo was based in Switzerland. Agilent was spun off in 1999 from Hewlett-Packard (“HP”). Tyloo was employed by HP from in or about April 1990, until in or about November 1999, at which time he was transferred to Agilent, within the international distributor operation at Agilent Technologies Europe B.V.

<sup>4</sup> Between on or about November 1, 2004, and on or about December 31, 2007, Technoline acted as a distributor/reseller of Agilent products through reseller agreements it executed with Agilent

that is subject to the Regulations, or in any other activity subject to the Regulations.

*Second*, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

*Third*, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to the Denied Person by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

*Fourth*, Tyloo shall not take any action or make or permit to be made any public statement, directly or indirectly, denying the allegations in the Proposed Charging Letter or this Order. The foregoing does not affect Tyloo's testimonial obligations in any proceeding; nor does it affect his right to take legal or factual positions in civil litigation or other civil proceedings in which the U.S. Department of Commerce is not a party.

*Fifth*, the Proposed Charging Letter, the Settlement Agreement, and this Order shall be made available to the public.

*Sixth*, this Order shall be served on Tyloo, and shall be published in the **Federal Register**.

This Order, which constitutes the final agency action in this matter, is effective immediately.

Issued this 10th day of January, 2017.

**Richard R. Majauskas**,

*Acting Assistant Secretary for Export Enforcement.*

[FR Doc. 2017-00893 Filed 1-13-17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-570-601]

#### **Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, and Rescission of New Shipper Review; 2014-2015**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On July 14, 2016, the Department of Commerce (Department) published the preliminary results of the 28th administrative and new shipper reviews of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished (TRBs), from the People's Republic of China (PRC). The period of review (POR) is June 1, 2014, through May 31, 2015. After analyzing the comments received, we made no changes to the margin calculations in the administrative review and we are rescinding the new shipper review (NSR). The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled "Final Results of the Review."

**DATES:** Effective January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Blaine Wiltse or Manuel Rey, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-6345 or (202) 482-5518, respectively.

#### **Background**

These final results of administrative review cover four exporters of the subject merchandise, Changshan Peer Bearing Co. Ltd. (CPZ/SKF), Haining Nice Flourish Auto Parts Co., Ltd. (Nice

Flourish), Roci International (HK) Limited (Roci), and Yantai CMC Bearing Co., Ltd. (Yantai CMC). The Department selected CPZ/SKF and Yantai CMC as mandatory respondents for individual examination; however, we subsequently found that Yantai CMC does not qualify for a separate rate. The NSR covers Shandong Bolong Bearing Co., Ltd. (Bolong).

On July 14, 2016, the Department published the *Preliminary Results*.<sup>1</sup> In the *Preliminary Results*, we found that Bolong's sale to the United States is not *bona fide*, as required by section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), and, therefore, we indicated that we intended to rescind the NSR.

In August 2016, we received case briefs from the Timken Company (the petitioner), Bolong and Yantai CMC. In September 2016, we received rebuttal briefs from the petitioner and CPZ/SKF. In October 2016, the Department held a public hearing in the administrative review at the request of the petitioner.

In November 2016, the Department extended the deadline for the final results by 60 days to January 10, 2017.<sup>2</sup>

The Department conducted this review in accordance with section 751 of the Act.

#### **Scope of the Order**<sup>3</sup>

The merchandise covered by the order includes tapered roller bearings and parts thereof. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. The HTSUS subheadings are provided for convenience and customs purposes

<sup>1</sup> See *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results, Partial Rescission of Antidumping Duty Administrative Review, and Preliminary Rescission of New Shipper Review; 2014-2015*, 81 FR 45455 (July 14, 2016) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

<sup>2</sup> See Memorandum from Manuel Rey, International Trade Compliance Analyst, Office II, Antidumping and Countervailing Duty Operations, to Christian Marsh, Deputy Assistant Secretary for AD/CVD Operations, entitled, "Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China: Extension of Deadline for the Final Results of Antidumping Duty Administrative, Changed Circumstances, and New Shipper Reviews," dated November 1, 2016.

<sup>3</sup> See *Notice of Antidumping Duty Order; Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China*, 52 FR 22667 (June 15, 1987) (*Order*).

only; the written description of the scope of the order is dispositive.<sup>4</sup>

### Separate Rates

In the *Preliminary Results*, we found that evidence provided by CPZ/SKF, Nice Flourish, and Roci supported finding an absence of both *de jure* and *de facto* government control, and, therefore, we preliminarily granted a separate rate to each of these companies.<sup>5</sup> We received no information since the issuance of the *Preliminary Results* that provides a basis for reconsidering these determinations. Therefore, for the final results, we continue to find that CPZ/SKF, Nice Flourish, and Roci are eligible for separate rates.

With respect to Yantai CMC, however, we determined in the *Preliminary Results* that this company failed to demonstrate an absence of *de facto* government control, and, thus, the Department did not grant Yantai CMC a separate rate. For these final results, we continue to find, based on record evidence, that Yantai CMC failed to demonstrate an absence of *de facto* government control. Accordingly, we are not granting Yantai CMC a separate rate. For further discussion of this issue, see Comments 2 through 5 of the accompanying Issues and Decision Memorandum.

### Weighted-Average Dumping Margin for the Non-Examined, Separate-Rate Companies

In accordance with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle Corp. v. United States*, we are applying to the exporters subject to this review that are determined to be eligible for a separate rate, but are not selected as individually examined respondents, the rate calculated for the mandatory respondent, CPZ/SKF, which is *de minimis*.<sup>6</sup>

### Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review and new shipper review are addressed in the Issues and

Decision Memorandum. A list of the issues which parties raised and to which we respond in the Issues and Decision Memo is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://trade.gov/enforcement>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

### Changes Since the Preliminary Results

Based on our analysis of the comments received, we made no changes in the margin calculation for CPZ/SKF.

### Rescission of New Shipper Review

For the reasons explained in the Issues and Decision Memorandum, the Department continues to find that Bolong's sale is non-*bona fide*. Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, and thus there are no reviewable transactions, the Department is rescinding the NSR.

### Period of Review

The POR is June 1, 2014, through May 31, 2015.

### Final Results of the Administrative Review

Because Yantai CMC did not demonstrate that it is entitled to a separate rate, the Department finds Yantai CMC to be part of the PRC-wide entity. No party requested a review of the PRC-wide entity. Therefore, we did not conduct a review of the PRC-wide entity and the entity's rate is not subject to change.<sup>7</sup> The rate previously established for the PRC-wide entity is 92.84 percent.

Additionally, we are assigning the following weighted-average dumping margins to the firms listed below for the period June 1, 2014, through May 31, 2015:

Exporters	Weighted-average dumping margin (percent)
Changshan Peer Bearing Co., Ltd .....	0.00
Haining Nice Flourish Auto Parts Co., Ltd* .....	0.00
Roci International (HK) Limited*	0.00

\* This company demonstrated eligibility for a separate rate in this administrative review.

### Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

### Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), the Department has determined, and Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise, where applicable, in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Pursuant to the *Final Modification for Reviews*,<sup>8</sup> because the above-listed respondents' weighted-average dumping margins are zero, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.<sup>9</sup>

For Yantai CMC, because the Department determined that this company did not qualify for a separate rate, we will instruct CBP to assess dumping duties on the company's entries of subject merchandise at the rate of 92.84 percent.

For Bolong, because the Department rescinded the NSR, the Department will instruct CBP to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise from Bolong. Bolong continues to be part of the PRC-wide entity and, therefore, we also will instruct CBP to assess dumping duties on the company's entries of subject merchandise at the rate of 92.84 percent.

For entries that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, the Department will

<sup>4</sup> For a complete description of the scope of the order, see the "Issues and Decision Memorandum for the Antidumping Duty Administrative Review (2014–2015): Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China," from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Antidumping and Countervailing Duty Operations, dated concurrently with, and adopted by, this notice (Issues and Decision Memo).

<sup>5</sup> *Id.*, at 2–5.

<sup>6</sup> See, *Albemarle Corp. & Subsidiaries v. United States*, 821 F.3d 1345 (Fed. Cir. 2016).

<sup>7</sup> See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity (NME) in NME Antidumping Duty Proceedings*, 78 FR 65963, 65970 (November 4, 2013).

<sup>8</sup> See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

<sup>9</sup> *Id.*, 77 FR at 8102.

instruct CBP to liquidate such entries at the PRC-wide rate.

### Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is *de minimis*, then a cash deposit rate of zero will be established for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that currently have separate a rate, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding where the exporter received that separate rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the PRC-wide entity, 92.84 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter.

These deposit requirements, when imposed, shall remain in effect until further notice.

### Notifications to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

### Notifications to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply

with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 10, 2017.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

### Appendix—List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Issues
  - a. Surrogate Value for Truck Freight
  - b. The Department Should Grant Yantai CMC a Separate Rate
  - c. The Denial of Separate Rate Status for Yantai CMC Is Not Supported by Record Evidence
  - d. The Rate Assigned to Yantai CMC
  - e. The Department's Separate Rates Test and the Rate Assigned to Yantai CMC Are Inconsistent With the WTO Agreements
  - f. The Department Should Continue the NSR and Calculate a Margin for the Final
5. Conclusion

[FR Doc. 2017-00827 Filed 1-13-17; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-580-816]

#### Certain Corrosion-Resistant Steel Flat Products From the Republic of Korea: Notice of Court Decision Not in Harmony With Final Results and Notice of Amended Final Results

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Court of International Trade (CIT or Court) sustained in full the Department of Commerce's (the Department) second remand results pertaining to the fifteenth administrative review of the antidumping duty order on certain corrosion-resistant steel flat products from the Republic of Korea covering the period of August 1, 2007, through July 31, 2008. The Department is notifying the public that the final judgment in this case is not in harmony with the final results of the administrative review, and that the Department is amending the final results with respect to the weighted-average dumping margins assigned to Union Steel Manufacturing Co., Ltd. (Union), Hyundai HYSCO (HYSCO), and Dongbu Steel Co., Ltd. (Dongbu).

**DATES:** Effective December 27, 2016.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Moore, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-3692.

### SUPPLEMENTARY INFORMATION:

#### Background

On March 15, 2010, the Department of Commerce (the Department) issued the *Final Results*.<sup>1</sup> Four parties contested the Department's findings in the *Final Results*. Three of the four plaintiffs, Union, HYSCO, and Dongbu, are Korean producers/exporters of certain corrosion-resistant steel flat products (CORE). Union and HYSCO were mandatory respondents in the fifteenth administrative review; Dongbu was an unexamined respondent subject to the non-selected rate. The remaining plaintiff, United States Steel Corporation (U.S. Steel), was a petitioner in the fifteenth administrative review.

In the *Final Results*, the Department assigned weighted-average dumping margins of 14.01 percent to Union and 3.29 percent to HYSCO.<sup>2</sup> As an unexamined respondent, Dongbu received the margin of 8.65 percent that the Department assigned to all unexamined respondents, which the Department calculated as a simple average of the non-*de-minimis* margins of the examined respondents.<sup>3</sup>

On May 25, 2012, the CIT issued its opinion in *Union Steel I*, which remanded various aspects of the *Final Results* to the Department.<sup>4</sup> In particular, the Court made the following holdings:

(1) the Department's decision to use financial data pertaining only to the 2008 fiscal year of Union's parent company in determining Union's interest expense ratio cannot be upheld on judicial review; (2) in response to defendant's request for a voluntary remand, the court will order the Department to reconsider the "quarterly cost methodology to apply the "recovery-of-costs" test to home-market sales of Union and HYSCO and the "indexing" methodology wherever used in the *Final Results*; (3) on remand, the Department must reconsider the use in the *Final Results* of the quarterly-cost and

<sup>1</sup> See *Certain Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Notice of Final Results of the Fifteenth Administrative Review*, 75 FR 13490 (March 22, 2010) (*Final Results*) and accompanying Decision Memorandum (Final Decision Memorandum).

<sup>2</sup> See *Final Results*, 75 FR at 13491.

<sup>3</sup> *Id.*

<sup>4</sup> See *Union Steel Mfg. Co. v. United States*, 837 F. Supp. 2d 1307 (Ct. Int'l Trade 2012) (*Union Steel I*).

indexing methodologies for various other purposes; (4) the Department must reconsider its decision to depart from its normal method for selecting comparison months of normal value sales; (5) in response to defendant's request for a voluntary remand, the court will order the Department to reconsider its decision to compare laminated CORE and non-laminated, painted CORE as "identical" merchandise; (6) in response to defendant's request for a voluntary remand, the court will order that Commerce reconsider the use of the zeroing methodology in the fifteenth review; (7) no relief is available on Dongbu's claim seeking an individually-determined dumping margin; and (8) in response to the defendant's request for a voluntary remand, remand is appropriate on U.S. Steel's challenge to the date of sale used for certain sales by HYSCO through a U.S. affiliate. The court determines, in addition, that any modifications to the weighted-average dumping margins of Union and HYSCO resulting from this remand shall be reflected in the rate applied to Dongbu.<sup>5</sup>

Pursuant to *Union Steel I*, the Department issued the First Remand Redetermination,<sup>6</sup> in which it addressed the Court's holdings and revised Union's margin from 14.01 percent to 9.85 percent and HYSCO's margin from 3.29 percent to 1.46 percent.<sup>7</sup> Again, based on a simple average of the margins calculated for Union and HYSCO, the Department changed Dongbu's margin from 8.65 percent to 5.56 percent.<sup>8</sup>

Following consideration of comments submitted to the CIT on the First Remand Redetermination and an oral argument, the Court issued its decision in *Union Steel II*, which affirmed in part, and remanded in part to the Department, various aspects of the First Remand Redetermination.<sup>9</sup> In particular, the Court remanded for the Department to address:

(1) the decision to make a major input adjustment when calculating Union's interest expense ratio; (2) the application of the modified "quarterly cost" methodology wherever used in the normal value calculations for Hyundai HYSCO . . . including the difference-in-merchandise ("DIFMER") adjustments and constructed value ("CV") determinations; (3) the application of the modified "quarterly cost" methodology for all aspects of the normal value calculations for Union except the revised sales-below-cost and recovery-of-costs tests; (4) the decision to depart from the normal method for selecting a comparison month when determining antidumping

margins for Union and HYSCO; and (5) the decision to depart from the normal method by selecting the date of shipment, rather than the date of invoice, as the date of sale for certain sales that HYSCO made through a U.S. affiliate, Hyundai HYSCO USA, Inc.<sup>10</sup>

The Court also instructed the Department to "recalculate the margin for Dongbu based on the redetermined margins for Union and HYSCO."<sup>11</sup>

In response to *Union Steel II*, the Department issued the Second Remand Redetermination in which it reconsidered the remanded issues and revised the 9.85 percent margin it previously determined for Union to 9.83 percent.<sup>12</sup> The Department revised HYSCO's margin from 1.46 percent to 5.56 percent.<sup>13</sup> Once again assigning Dongbu a margin based on a simple average of the Union and HYSCO margins, the Department changed Dongbu's margin from 5.56 percent to 7.70 percent.<sup>14</sup>

In *Union Steel III*, the CIT sustained in full the Department's Second Remand Redetermination.<sup>15</sup> In particular, the CIT sustained the Department's decision to depart from its 90/60-day window period regulation and to instead limit comparisons of individual U.S. sales to home market sales that occurred during the same quarter, based on the fact that the Department had relied on its quarterly cost methodology because there were significantly changing costs throughout the review period.<sup>16</sup> Furthermore, the Court sustained the Department's determination to rely on invoice date instead of shipment date for determining the date of sale for HYSCO's U.S. sales in the Second Remand Redetermination, because certain evidence in HYSCO's questionnaire responses indicated that price remained subject to change after shipment.<sup>17</sup> Finally, the Court sustained four other aspects of the Second Remand Redetermination, which were not challenged by any party: (1) The Department's calculation of Union Steel's interest expense ratio; (2) the Department's modification to its cost-recovery test as applied to HYSCO on remand, in which the Department discontinued relying on surrogate costs and relied instead on HYSCO's actual

costs from the quarters in which there was production during the period of review; (3) the Department's decision to use unindexed quarterly cost data to calculate CV and DIFMER adjustments; and (4) the Department's use of a surrogate-based method in calculating CV and DIFMER adjustments, which was different than the method used when applying its cost-recovery test to HYSCO in the Department's First Remand Redetermination, which the Court had found objectionable in *Union Steel II*.<sup>18</sup>

Thus, in *Union Steel III*, the Court affirmed the following dumping margins as calculated by the Department in the Second Remand Redetermination: 9.83 percent for Union, 5.56 percent for HYSCO, and 7.70 percent for Dongbu.

#### Timken Notice

In its decision in *Timken*,<sup>19</sup> as clarified by *Diamond Sawblades*,<sup>20</sup> the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), the Department must publish a notice of a court decision that is not "in harmony" with a Department determination and must suspend liquidation of entries pending a "conclusive" court decision. The CIT's December 15, 2016, final judgement sustaining the Second Remand Redetermination constitutes a final decision of the Court that is not in harmony with the Department's *Final Results*. This notice is published in fulfillment of the publication requirements of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending a final and conclusive court decision.

#### Amended Final Results

Because there is now a final court decision, we are amending the *Final Results* with respect to the dumping margins calculated for Union, HYSCO, and Dongbu. Based on the Second Remand Redetermination, as affirmed by the CIT in *Union Steel III*, the revised dumping margins for Union, HYSCO, and Dongbu are 9.83 percent, 5.56 percent, and 7.70 percent, respectively.

In the event that the CIT's rulings are not appealed or, if appealed, is upheld by a final and conclusive court decision, the Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on

<sup>10</sup> *Id.*, at 1300, 1327–28.

<sup>11</sup> *Id.*

<sup>12</sup> See *Results of Redetermination Pursuant to Remand*, at 44 (Aug. 1, 2014) (Second Remand Redetermination).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> See *Union Steel Mfg. Co. v. United States*, Ct. Int'l Trade Slip Op. 16–117 (Dec. 15, 2016) (*Union Steel III*), at 2, 26.

<sup>16</sup> *Id.*, at 16–20.

<sup>17</sup> *Id.*, at 11–13.

<sup>5</sup> *Id.*, at 1310, 1337–38.

<sup>6</sup> See *Results of Redetermination Pursuant to Remand* (Sept. 24, 2012) (First Remand Redetermination).

<sup>7</sup> See First Remand Redetermination at 67.

<sup>8</sup> *Id.*

<sup>9</sup> See *Union Steel Mfg. Co. v. United States*, 968 F. Supp. 2d 1297 (Ct. Int'l Trade 2014) (*Union Steel II*).

<sup>18</sup> *Id.*, at 5–11.

<sup>19</sup> See *Timken Co. v. United States*, 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

<sup>20</sup> See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

unliquidated entries of subject merchandise based on the revised dumping margins listed above.

#### Cash Deposit Requirements

The Department notified CBP to discontinue the collection of cash deposits on entries of the subject merchandise, entered or withdrawn from warehouse, on or after February 14, 2012, due to the revocation of the order.<sup>21</sup> Therefore, no cash deposit requirements will be imposed as a result of these amended final results.

#### Notice to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: January 10, 2017.

#### Paul Piquado,

Assistant Secretary for Enforcement and Compliance,

[FR Doc. 2017-00882 Filed 1-13-17; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-533-869]

#### Certain New Pneumatic Off-the-Road Tires From India: Final Negative Determination of Sales at Less Than Fair Value and Final Determination of Critical Circumstances

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Department) determines that imports of certain new pneumatic off-the-road tires (OTR tires) from India are not being, or are not likely to be, sold in the United States at less than fair value (LTFV). The final estimated weighted-average dumping margins of sales at LTFV are listed below in the section entitled "Final Determination." The finding for whether critical circumstances exist for producers and exporters subject to the all-others rate is moot because the antidumping duty margins for Alliance Tires Private Limited (ATC) and Balkrishna Industries Limited (BKT) are zero. The period of investigation is January 1, 2015, through December 31, 2015.

**DATES:** Effective January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Lilit Astvatsatrian or Trisha Tran, AD/CVD Operations, Office IV, Enforcement and

Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-6412, or (202) 482-4852, respectively.

#### SUPPLEMENTARY INFORMATION:

##### Background

On August 19, 2016, the Department published the *Preliminary Determination* in the **Federal Register**.<sup>1</sup> In the *Preliminary Determination*, we postponed the final determination until no later than 135 days after the date of publication of the *Preliminary Determination* in accordance with section 735(a)(2) of the Tariff Act of 1930, as amended (the Act).<sup>2</sup>

A summary of the events that occurred since the Department published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.<sup>3</sup> The Issues and Decision Memorandum is a public document, and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>, and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

##### Scope Comments

In accordance with the *Preliminary Determination*, the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.<sup>4</sup> In

<sup>1</sup> See *Certain New Pneumatic Off-the-Road Tires: Negative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 81 FR 55431 (August 19, 2016) ("*Preliminary Determination*") and accompanying Preliminary Decision Memorandum.

<sup>2</sup> See *Preliminary Determination*, 81 FR at 55432.

<sup>3</sup> See Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance "Certain New Pneumatic Off-the-Road Tires from India: Issues and Decision Memorandum for the Final Determination of Sales at Less Than Fair Value," dated concurrently with this determination and hereby adopted by this notice ("Issues and Decision Memorandum").

<sup>4</sup> See *Preliminary Determination*, 81 FR at 55432, and accompanying Preliminary Decision Memorandum at "Scope Comments."

the *Preliminary Determination*, we did not modify the scope language as it appeared in the *Initiation Notice*.<sup>5</sup> No interested party submitted scope comments in case or rebuttal briefs. Therefore, the scope of this investigation remains unchanged for this final determination.<sup>6</sup>

##### Scope of the Investigation

The products covered by this investigation are OTR tires from India. For a complete description of the scope of the investigation, see Appendix I of this notice.

##### Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of these issues is attached to this notice at Appendix II.

##### Verification

As provided in section 782(i) of the Act, in August and September 2016, we conducted sales and cost verifications of the questionnaire responses submitted by ATC and BKT. We used standard verification procedures, including an examination of relevant accounting and production records, as well as original source documents provided by both respondents.

##### Changes to the Dumping Margin Calculations Since the Preliminary Determination

Based on our analysis of the comments received, pre-verification findings, and our findings at verification, we made certain changes to the dumping margin calculations for each respondent, ATC and BKT. For a discussion of these changes, see the Issues and Decision Memorandum.

##### Use of Adverse Facts Available

The Department has relied on partial adverse facts available under sections 776(a) and (b) of the Act.<sup>7</sup> A full discussion of our decision to rely on adverse facts available is presented in the Issues and Decision Memorandum.

<sup>5</sup> *Id.*; see also *Certain New Pneumatic Off-the-Road Tires from India and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations*, 81 FR 7073 (February 10, 2016) ("*Initiation Notice*").

<sup>6</sup> The Department has added two additional subheadings from the Harmonized Tariff Schedule of the United States to the list included for convenience and customs purposes since the *Preliminary Determination*. No revisions were made to the written description of the subject merchandise.

<sup>7</sup> See Sections 776(a) and (b) of the Act.

<sup>21</sup> See *Corrosion-Resistant Carbon Steel Flat Products from Germany and the Republic of Korea: Revocation of Antidumping and Countervailing Duty Orders*, 78 FR 16832, 16833 (March 19, 2013).



### Final Determination of Critical Circumstances

On December 9, 2016, Petitioners<sup>8</sup> filed a timely critical circumstances allegation pursuant to section 733(e)(1) of the Act and 19 CFR 351.206(b), alleging that critical circumstances exist with respect to imports of the merchandise under consideration.<sup>9</sup> The finding of whether critical circumstances exist with respect to producers and exporters subject to the all others rate is moot because the antidumping duty margins for ATC and BKT are zero.

### Final Determination

The Department determines, as provided in section 735 of the Act, that the following weighted-average dumping margins exist for the period January 1, 2015 through December 31, 2015:

Exporter/producer	Weighted-average margin (percent)	Cash deposit adjusted for subsidy offset
ATC Tires Private Ltd.	0.00	Not Applicable.
Balkrishna Industries Limited.	0.00	Not Applicable.
All-Others .....	0.00	Not Applicable.

Consistent with section 735(c)(1) of the Act, the Department has not determined an estimated all-others rate because it has not made an affirmative final determination of sales at LTFV.

### Suspension of Liquidation

Because the Department has not made an affirmative final determination of sales at LTFV, we are not directing U.S. Customs and Border Protection to suspend liquidation of any entries of OTR tires from India.

In the final determination of the companion countervailing duty investigation of OTR tires from India, the Department determined that the all other companies received a benefit from export subsidies.<sup>10</sup> In the instant investigation, the antidumping duty margins ATC and BKT are zero and no cash deposits will be collected. Therefore, no adjustment is required for export subsidies pursuant to sections

<sup>8</sup> Titan Tire Corporation (Titan) and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC (USW) (collectively, Petitioners).

<sup>9</sup> Letter from ATC, "Certain New Pneumatic Off-the-Road Tires from India—Petitioners' Critical Circumstances Allegation," dated December 9, 2016.

<sup>10</sup> See *Countervailing Duty Investigation of Certain New Pneumatic Off-the-Road Tires from India: Final Affirmative Determination, and Final Affirmative Critical Circumstances Determination, in Part*, dated concurrently with this notice.

735(c)(1) and 772(c)(1)(C) of the Act and 19 CFR 351.210(d).

### Disclosure

We will disclose the calculations performed to interested parties in this proceeding within five days of the date of announcement, in accordance with 19 CFR 351.224(b).

### U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission of our final determination.

### Notification Regarding Administrative Protective Orders (APOs)

This notice will serve as a reminder to parties subject to APOs of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination and notice are issued and published in accordance with sections 735(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: January 3, 2017.

### Paul Piquado,

*Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Investigation

The scope of this investigation is certain new pneumatic off-the-road tires (certain off road tires). Certain off road tires are tires with an off road tire size designation. The tires included in the scope may be either tube-type<sup>11</sup> or tubeless, radial, or non-radial, regardless of whether for original equipment manufacturers or the replacement market.

Subject tires may have the following prefix or suffix designation, which appears on the sidewall of the tire:

Prefix designations:

DH—Identifies a tire intended for agricultural and logging service which must be mounted on a DH drop center rim.

VA—Identifies a tire intended for agricultural and logging service which must be mounted on a VA multipiece rim.

IF—Identifies an agricultural tire to operate at 20 percent higher rated load than standard metric tires at the same inflation pressure.

VF—Identifies an agricultural tire to operate at 40 percent higher rated load than

<sup>11</sup> While tube-type tires are subject to the scope of this proceeding, tubes and flaps are not subject merchandise and therefore are not covered by the scope of this proceeding, regardless of the manner in which they are sold (e.g., sold with or separately from subject merchandise).

standard metric tires at the same inflation pressure.

Suffix designations:

ML—Mining and logging tires used in intermittent highway service.

DT—Tires primarily designed for sand and paver service.

NHS—Not for Highway Service.

TG—Tractor Grader, off-the-road tire for use on rims having bead seats with nominal +0.188" diameter (not for highway service).

K—Compactor tire for use on 5° drop center or semi-drop center rims having bead seats with nominal minus 0.032 diameter.

IND—Drive wheel tractor tire used in industrial service.

SL—Service limited to agricultural usage.

FI—Implement tire for agricultural towed highway service.

CFO—Cyclic Field Operation.

SS—Differentiates tires for off-highway vehicles such as mini and skid-steer loaders from other tires which use similar size designations such as 7.00-15TR and 7.00-15NHS, but may use different rim bead seat configurations.

All tires marked with any of the prefixes or suffixes listed above in their sidewall markings are covered by the scope regardless of their intended use.

In addition, all tires that lack any of the prefixes or suffixes listed above in their sidewall markings are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the following sections of the Tire and Rim Association Year Book, as updated annually, unless the tire falls within one of the specific exclusions set forth below. The sections of the Tire and Rim Association Year Book listing numerical size designations of covered certain off road tires include:

The table of mining and logging tires included in the section on Truck-Bus tires;

The entire section on Off-the-Road tires;

The entire section on Agricultural tires;

and

The following tables in the section on Industrial/ATV/Special Trailer tires:

- Industrial, Mining, Counterbalanced Lift Truck (Smooth Floors Only);

- Industrial and Mining (Other than Smooth Floors);

- Construction Equipment;

- Off-the-Road and Counterbalanced Lift Truck (Smooth Floors Only);

- Aerial Lift and Mobile Crane; and

- Utility Vehicle and Lawn and Garden Tractor.

Certain off road tires, whether or not mounted on wheels or rims, are included in the scope. However, if a subject tire is imported mounted on a wheel or rim, only the tire is covered by the scope. Subject merchandise includes certain off road tires produced in the subject countries whether mounted on wheels or rims in a subject country or in a third country. Certain off road tires are covered whether or not they are accompanied by other parts, e.g., a wheel, rim, axle parts, bolts, nuts, etc. Certain off road tires that enter attached to a vehicle are not covered by the scope.

Specifically excluded from the scope are passenger vehicle and light truck tires, racing



tires, mobile home tires, motorcycle tires, all-terrain vehicle tires, bicycle tires, on-road or on-highway trailer tires, and truck and bus tires. Such tires generally have in common that the symbol "DOT" must appear on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Such excluded tires may also have the following prefixes and suffixes included as part of the size designation on their sidewalls:

Prefix letter designations:

AT—Identifies a tire intended for service on All-Terrain Vehicles;

P—Identifies a tire intended primarily for service on passenger cars;

LT—Identifies a tire intended primarily for service on light trucks;

T—Identifies a tire intended for one-position "temporary use" as a spare only; and

ST—Identifies a special tire for trailers in highway service.

Suffix letter designations:

TR—Identifies a tire for service on trucks, buses, and other vehicles with rims having specified rim diameter of nominal plus 0.156" or plus 0.250";

MH—Identifies tires for Mobile Homes;

HC—Identifies a heavy duty tire designated for use on "HC" 15" tapered rims used on trucks, buses, and other vehicles. This suffix is intended to differentiate among tires for light trucks, and other vehicles or other services, which use a similar designation.

Example: 8R17.5 LT, 8R17.5 HC;

LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service;

ST—Special tires for trailers in highway service; and

M/C—Identifies tires and rims for motorcycles.

The following types of tires are also excluded from the scope: Pneumatic tires that are not new, including recycled or retreaded tires and used tires; non-pneumatic tires, including solid rubber tires; aircraft tires; and turf, lawn and garden, and golf tires. Also excluded from the scope are mining and construction tires that have a rim diameter equal to or exceeding 39 inches. Such tires may be distinguished from other tires of similar size by the number of plies that the construction and mining tires contain (minimum of 16) and the weight of such tires (minimum 1500 pounds).

The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.1025, 4011.20.1035, 4011.20.5030, 4011.20.5050, 4011.61.0000, 4011.62.0000, 4011.63.0000, 4011.69.0050, 4011.92.0000, 4011.93.4000, 4011.93.8000, 4011.94.4000, 4011.94.8000, 8431.49.9038, 8431.49.9090, 8709.90.0020, and 8716.90.1020. Tires meeting the scope description may also enter under the following HTSUS subheadings:

4011.99.4550, 4011.99.8550, 8424.90.9080, 8431.20.0000, 8431.39.0010, 8431.49.1090, 8431.49.9030, 8432.90.0005, 8432.90.0015, 8432.90.0030, 8432.90.0080, 8433.90.5010, 8503.00.9560, 8708.70.0500, 8708.70.2500, 8708.70.4530, 8716.90.5035, 8716.90.5055,

8716.90.5056 and 8716.90.5059. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

## Appendix II

### List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. List of Issues

III. Background

IV. Scope of the Investigation

V. Discussion of the Issues:

Comment 1: Standard Differential Pricing Methodology

Comment 2: Unreported U.S. Sample Sales

Comment 3: Sales Outside the Ordinary Course of Trade

Comment 4: Commission Offset

Comment 5: ATC's Revised Cost Database Submitted After Verification

Comment 6: Affirmative Determination of ATC

Comment 7: Correction of Minor Errors from U.S. Sales Verification

Comment 8: Warrantly

Comment 9: Other Discounts

Comment 10: Classification of BKT's Sales

Comment 11: Duty Drawback

Comment 12: CEP Offset

Comment 13: Quantity Unit of Measure

Comment 14: Correction of Verification Errors

Comment 15: Correction of *Preliminary Determination* Errors

VI. Recommendation

[FR Doc. 2017-00869 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[C-570-050]

#### Ammonium Sulfate From the People's Republic of China: Final Affirmative Countervailing Duty Determination

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (the Department) determines that countervailable subsidies are being provided to producers and exporters of ammonium sulfate from the People's Republic of China (PRC). The period of investigation is January 1, 2015 through December 31, 2015.

**DATES:** Effective January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Robert Galantucci, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-2923.

**SUPPLEMENTARY INFORMATION:**

## Background

On November 2, 2016, the Department published its preliminary affirmative determination that countervailable subsidies are being provided to producers and exporters of ammonium sulfate from the PRC in the **Federal Register**.<sup>1</sup> We invited interested parties to comment on our *Preliminary Determination*, and/or request a hearing. No party, including the mandatory respondents<sup>2</sup> and the Government of China (GOC), submitted comments or requested a hearing.

## Scope of the Investigation

The product covered by this investigation is ammonium sulfate from the PRC. For a complete description of the scope of this investigation, see Appendix II.

## Verification

None of the mandatory respondents in this investigation provided information requested by the Department. Hence, no verification was conducted.

## Use of Adverse Facts Available (AFA)

As discussed above, we received no comments from interested parties pertaining to the *Preliminary Determination*. Therefore, for this final determination, and pursuant to sections 776(a)-(d) of the Tariff Act of 1930, as amended (the Act), we continue to rely on facts available for Wuzhoufeng AST and Yantai AMP, the two mandatory respondents, and the GOC, which did not respond to our countervailing duty questionnaires.<sup>3</sup> Further, we continue to find that Wuzhoufeng AST, Yantai AMP, and the GOC failed to act to the best of their ability and, therefore, we are drawing an adverse inference in selecting from among the facts otherwise available to determine whether the programs subject to this investigation constitute countervailable subsidies and to calculate the *ad valorem* rates for Wuzhoufeng AST and Yantai AMP.<sup>4</sup>

For this final determination, as AFA, we continue to find all programs

<sup>1</sup> See *Countervailing Duty Investigation of Ammonium Sulfate from the People's Republic of China: Preliminary Affirmative Determination*, 81 FR 76332 (November 2, 2016) (*Preliminary Determination*).

<sup>2</sup> The Department selected Wuzhoufeng Agricultural Science & Technology Co. Ltd. (Wuzhoufeng AST) and Yantai Jiahe Agriculture Means of Production Co. Ltd. (Yantai AMP) as mandatory respondents.

<sup>3</sup> See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination in the Countervailing Duty Investigation of Ammonium Sulfate from the People's Republic of China," dated October 24, 2016 (*Preliminary Decision Memorandum*) at 1-2, 5-7 and Attachment 1.

<sup>4</sup> See sections 776(a) and (b) of the Act.

included in this proceeding to be countervailable, *i.e.*, they provide a financial contribution within the meaning of sections 771(5)(B)(i) and (D) of the Act, confer a benefit within the meaning of section 771(5)(E) of the Act, and are specific within the meaning of section 771(5A) of the Act.<sup>5</sup> The Department's calculation of the AFA rate was discussed in the Preliminary Decision Memorandum which is incorporated by reference, and hereby adopted by, this final determination.<sup>6</sup> The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>, and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

### Final Determination

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated countervailing duty rates for the individually investigated producers/exporters of the subject merchandise, Wuzhoufeng AST and Yantai AMP.

With respect to the "all-others" rate, section 705(c)(5)(A)(ii) of the Act provides that if the countervailing duty rates established for all exporters and producers individually investigated are determined entirely in accordance with section 776 of the Act, the Department may use any reasonable method to establish an all-others rate for exporters and producers not individually investigated. In this case, the rates assigned to Wuzhoufeng AST and Yantai AMP are based entirely on facts otherwise available, with adverse inferences, under section 776 of the Act. Because there is no other information on the record with which to determine an all-others rate, in accordance with section 705(c)(5)(A)(ii) of the Act, we have established the all-others rate by applying the countervailable subsidy rates for mandatory respondents Wuzhoufeng AST and Yantai AMP. The final countervailable subsidy rates are summarized in the table below.

Company	Subsidy rate (percent)
Wuzhoufeng Agricultural Science & Technology Co. Ltd .....	206.72
Yantai Jiaye Agriculture Means of Production Co. Ltd .....	206.72
All-Others .....	206.72

### Suspension of Liquidation

As a result of our *Preliminary Determination*, and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend all entries of ammonium sulfate from the PRC, as described in the "Scope of the Investigation," that were entered, or withdrawn from warehouse, for consumption on or after November 2, 2016, the date of the publication of the *Preliminary Determination* in the **Federal Register**. Additionally, at that time, we instructed CBP to collect cash deposits of estimated countervailing duties at the rates determined in the *Preliminary Determination*.<sup>7</sup> The suspension of liquidation and collection of cash deposits will remain in effect until further notice.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and will instruct CBP to continue to suspend liquidation under section 706(a) of the Act and to continue to require a cash deposit of estimated CVDs for such entries of merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited, or securities posted as a result of the suspension of liquidation, will be refunded or canceled.

### Disclosure

We described the calculations used to determine CVD rates based on AFA in the Preliminary Decision Memorandum.<sup>8</sup> Thus, no additional disclosure of calculations is necessary for this final determination.

### ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all

privileged and business proprietary information in our files, provided the ITC confirms it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

### Notification Regarding APOs

This notice will serve as a reminder to the parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APOs in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

Dated: January 9, 2017.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope Comments
- IV. Scope of the Investigation
- V. Injury Test
- VI. Application of the CVD Law to Imports From the PRC
- VII. Use of Facts Otherwise Available and Adverse Inferences
- VIII. Calculation of the All-Others Rate
- IX. ITC Notification
- X. Public Comment
- XI. Conclusion

### Appendix II

#### Scope of the Investigation

The merchandise covered by this investigation is ammonium sulfate in all physical forms, with or without additives such as anti-caking agents. Ammonium sulfate, which may also be spelled as ammonium sulphate, has the chemical formula (NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>.

The scope includes ammonium sulfate that is combined with other products, including by, for example, blending (*i.e.*, mixing granules of ammonium sulfate with granules of one or more other products), compounding (*i.e.*, when ammonium sulfate is compacted with one or more other products under high pressure), or granulating (incorporating multiple products into granules through, *e.g.*, a slurry process). For such combined products, only the ammonium sulfate component is covered by the scope of this investigation.

Ammonium sulfate that has been combined with other products is included within the scope regardless of whether the

<sup>7</sup> See *Preliminary Determination*, 81 FR at 76332.

<sup>8</sup> See *Preliminary Decision Memorandum* at "Application of AFA: Wuzhoufeng AST and Yantai AMP, and the GOC."

<sup>5</sup> See *Preliminary Decision Memorandum* at 6–10.

<sup>6</sup> See *id.* at Attachment 1.

combining occurs in countries other than China.

Ammonium sulfate that is otherwise subject to this investigation is not excluded when commingled (*i.e.*, mixed or combined) with ammonium sulfate from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The Chemical Abstracts Service (CAS) registry number for ammonium sulfate is 7783–20–2.

The merchandise covered by this investigation is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 3102.21.0000. Although this HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

[FR Doc. 2017–00843 Filed 1–13–17; 8:45 am]

BILLING CODE 3510–DS–P

**DEPARTMENT OF COMMERCE**

**International Trade Administration**

[A–570–898]

**Chlorinated Isocyanurates From the People’s Republic of China: Final Results of Antidumping Duty Administrative Review; 2014–2015**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On July 12, 2016, the Department of Commerce (“the Department”) published its *Preliminary Results* of the administrative review of the antidumping duty order on chlorinated isocyanurates (“chloro isos”) from the People’s Republic of China (“the PRC”). The period of review (POR) is June 1, 2014, through May 31, 2015. This review covers three producers/exporters: (1) Heze Huayi Chemical Co., Ltd. (“Heze Huayi”); (2) Hebei Jiheng Chemical Co., Ltd. (“Jiheng”); and (3) Juancheng Kangtai Chemical Co., Ltd. (“Kangtai”). We invited parties to comment on our *Preliminary Results*. Based on our analysis of the comments received, we made certain changes to our margin calculations for all three respondents. The final dumping margins for this review are listed in the “Final Results” section below.

**DATES:** Effective January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3964.

**Background**

On July 12, 2016, the Department published its *Preliminary Results* of the administrative review.<sup>1</sup> On August 25, 2016, respondents Heze Huayi, Kangtai, Jiheng, collectively submitted a case brief.<sup>2</sup> On September 6, 2016, Biolab, Inc., Clearon Corp. and Occidental Chemical Corp. (collectively, “Petitioners”) submitted a rebuttal brief.<sup>3</sup>

On October 21, 2016, the Department fully extended the deadline for the final results in this administrative review until January 9, 2017.<sup>4</sup> The Department held a public hearing on December 14, 2016, to address issues raised in the case and rebuttal briefs.<sup>5</sup>

**Scope of the Order**

The products covered by the order are chloro isos, which are derivatives of cyanuric acid, described as chlorinated s-triazine triones. Chlorinated isos are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.40.50, 3808.50.40 and 3808.94.5000 of the Harmonized Tariff Schedule of the United States. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of merchandise subject to the scope is dispositive. For a full description of the scope of the order, *see* Issues and Decision Memorandum.<sup>6</sup>

<sup>1</sup> *See Chlorinated Isocyanurates from the People’s Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015*, 81 FR 45128 (July 12, 2016) (*Preliminary Results*).

<sup>2</sup> *See* “Chlorinated Isocyanurates from the People’s Republic of China: Case Brief,” (August 25, 2016).

<sup>3</sup> *See* “The Administrative Review of the Antidumping Duty Order on Chlorinated Isocyanurates from the People’s Republic of China: Rebuttal Brief of Biolab, Inc., Clearon Corp. and Occidental Chemical Corporation,” (September 6, 2016).

<sup>4</sup> *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, “Chlorinated Isocyanurates from the People’s Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,” (October 21, 2016).

<sup>5</sup> *See* Hearing Transcript, “Public Hearing in the Matter of: Administrative Review under the Antidumping Duty Order on Chlorinated Isocyanurates from the People’s Republic of China,” (December 20, 2016).

<sup>6</sup> *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, “Decision Memorandum for the Final Results of Antidumping Duty Administrative Review: Chlorinated Isocyanurates from the People’s Republic of China; 2014–2015,” (“Issues and Decision Memorandum”) issued concurrently with this notice for a complete description of the scope of the Order.

**Analysis of Comments Received**

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum follows as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (“ACCESS”). ACCESS is available to registered users at <http://access.trade.gov> and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and electronic versions of the Issues and Decision Memorandum are identical in content.

**Changes Since the Preliminary Results**

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results*, we have made revisions to the margin calculations for all three companies as a result of changes in the surrogate financial ratios and the surrogate value for steam coal.<sup>7</sup>

**Final Results of Administrative Review**

The weighted-average dumping margins for the administrative review are as follows:

Exporter	Weighted-average dumping margin (percent)
Heze Huayi Chemical Co., Ltd ...	53.95
Hebei Jiheng Chemical Co., Ltd	61.03
Juancheng Kangtai Chemical Co., Ltd .....	35.05

**Assessment Rates**

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (the “Act”), and 19 CFR 351.212(b), the Department has determined, and U.S. Customs and Border Protection (“CBP”) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP

<sup>7</sup> *See* Issues and Decision Memorandum, at 1.

15 days after publication of the final results of this administrative review.

Where the respondent reported reliable entered values, we calculated importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).<sup>8</sup> Where the Department calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, the Department will direct CBP to assess importer-specific assessment rates based on the resulting per-unit rates.<sup>9</sup> Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (i.e., 0.50 percent), the Department will instruct CBP to collect the appropriate duties at the time of liquidation.<sup>10</sup> Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis*, the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.<sup>11</sup>

Pursuant to the Department's assessment practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide entity rate. Additionally, if the Department determines that an exporter had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (i.e., at that exporter's rate) will be liquidated at the PRC-wide entity rate.<sup>12</sup>

#### Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis*, a zero cash deposit rate will be required for that

company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the existing producer/exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be eligible for a separate rate, the cash deposit rate will be the PRC-wide rate of 285.63 percent;<sup>13</sup> and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

#### Disclosure

We intend to disclose the calculations performed regarding these final results within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

#### Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and that subsequent assessment of doubled antidumping duties.

#### Administrative Protective Order Notification to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these final results of administrative review in

accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h).

Dated: January 9, 2017.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

#### Appendix—Issues and Decision Memorandum

Summary  
Background  
Scope of the Order  
Changes Since the Preliminary Results  
Discussion of the Issues  
    Comment 1: Selection of the Primary Surrogate Country  
    Comment 2: Selection of Mexican Surrogate Value Information over the Romanian Surrogate Value Information  
        A. Surrogate Financial Ratios  
        B. Surrogate Values for Certain Other Inputs  
Recommendation  
[FR Doc. 2017-00825 Filed 1-13-17; 8:45 am]  
BILLING CODE 3510-DS-P

#### DEPARTMENT OF COMMERCE

#### International Trade Administration

[A-570-601]

#### Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Changed Circumstances Review and Reinstatement of Shanghai General Bearing Co., Ltd. in the Antidumping Duty Order

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On July 13, 2016, the Department of Commerce (the Department) published the preliminary results of the changed circumstances review and intent to reinstate Shanghai General Bearing Co., Ltd. (SGBC/SKF) in the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished, (TRBs) from the People's Republic of China (PRC). This review covers TRBs from the PRC manufactured and exported by SGBC/SKF. The period of review is June 1, 2014, through May 31, 2015. Based on our analysis of the comments received, we made changes to the margin calculations. Therefore, the final results differ from the preliminary results. Further, we continue to determine that SGBC/SKF sold TRBs at less than normal value (NV), and, as a result, we are reinstating SGBC/SKF in the antidumping order on TRBs from the PRC. The final weighted-average dumping margin is listed below in the

<sup>8</sup> See 19 CFR 351.212(b)(1).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> See 19 CFR 351.106(c)(2).

<sup>12</sup> See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

<sup>13</sup> For an explanation on the derivation of the PRC-wide rate, see *Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates from the People's Republic of China*, 70 FR 24502, 24505 (May 10, 2005).

section entitled “Final Results of Review.”

**DATES:** Effective January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Alice Maldonado, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-4682.

**SUPPLEMENTARY INFORMATION:**

**Background**

On July 13, 2016, the Department published the preliminary results of this changed circumstances review and intent to reinstate SGBC/SKF in the antidumping duty order on TRBs from the PRC.<sup>1</sup> This review covers TRBs from the PRC manufactured and exported by SGBC/SKF. The period of review is June 1, 2014, through May 31, 2015.

In August 2016, we received case briefs from the Timken Company (the petitioner) and SGBC/SKF; we also received a letter in lieu of a case brief from Stemco LP (Stemco), an interested party in the proceeding, in which Stemco supported the arguments made in the petitioner’s case brief. In September 2016, we received rebuttal briefs from the petitioner and SGBC/SKF. In October 2016, the Department held a public hearing at the request of the petitioner.

The Department conducted this changed circumstances review in accordance with section 751(b)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.216(d).

**Scope of the Order**

The merchandise covered by the order<sup>2</sup> includes tapered roller bearings and parts thereof, finished and unfinished, from the PRC; flange, take up cartridge, and hanger units incorporating tapered roller bearings; and tapered roller housings (except pillow blocks) incorporating tapered rollers, with or without spindles, whether or not for automotive use. These products are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) item numbers 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20,

8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. Although the HTSUS item numbers are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.<sup>3</sup>

**Basis for Reinstatement**

In requesting revocation, pursuant to 19 CFR 353.25(b) (1996) and 19 CFR 353.25(a)(2)(iii) (1996),<sup>4</sup> SGBC/SKF agreed to immediate reinstatement of the order, so long as any exporter or producer is subject to the order, if the Secretary concludes that subsequent to the revocation, SGBC/SKF sold TRBs at less than NV.<sup>5</sup> Under 19 CFR 353.25(a)(2)(iii) (1996), as long as any exporter or producer is subject to an antidumping duty order which remains in force, an entity previously granted a revocation may be reinstated under that order if it is established that the entity has resumed the dumping of subject merchandise.

In this case, because other exporters in the PRC remain subject to the TRBs order, the order remains in effect, and SGBC/SKF may be reinstated in the order. The Department granted SGBC/SKF revocation based, in part, upon its agreement to immediate reinstatement in the antidumping duty order if the Department were to find that the company resumed dumping of TRBs from the PRC.<sup>6</sup>

As discussed in the Issues and Decision Memo, we examined SGBC/SKF’s response and preliminarily found

that SGBC/SKF’s dumping margin for the review period is greater than *de minimis*. Accordingly, we are reinstating SGBC/SKF in the antidumping duty order on TRBs from the PRC.

**Analysis of Comments Received**

All issues raised in the case and rebuttal briefs by parties to this changed circumstances review are addressed in the Issues and Decision Memo. A list of the issues which parties raised and to which we respond in the Issues and Decision Memo is attached to this notice as an Appendix. The Issues and Decision Memo is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memo can be accessed directly at <http://enforcement.trade.gov/firn/>. The signed Issues and Decision Memo and the electronic version of the Issues and Decision Memo are identical in content.

**Changes Since the Preliminary Results**

Based on our analysis of the comments received, we made changes in the margin calculation for SGBC/SKF. These changes are discussed in the relevant sections of the Issues and Decision Memo.

**Final Results of Review**

The Department determines that the following weighted-average dumping margin exists for the period June 1, 2014, through May 31, 2015:

Manufacturer/exporter	Weighted-average dumping margin (percent)
Shanghai General Bearing Co., Ltd. ....	5.82

**Disclosure**

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

**Cash Deposit Requirements**

Because we established that TRBs from the PRC manufactured and exported by SGBC/SKF are being sold at less than NV, SGBC/SKF is hereby

<sup>1</sup> See *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People’s Republic of China: Preliminary Results of Changed Circumstances Review and Intent To Reinstate Shanghai General Bearing Co., Ltd. in the Antidumping Duty Order*, 81 FR 45282 (July 13, 2016) (CCR Preliminary Results).

<sup>2</sup> See *Notice of Antidumping Duty Order; Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People’s Republic of China*, 52 FR 22667 (June 15, 1987) (Order).

<sup>3</sup> For a complete description of the scope of the Order, see the “Issues and Decision Memorandum for the Antidumping Duty Changed Circumstances Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People’s Republic of China,” from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Antidumping and Countervailing Duty Operations, dated concurrently with, and adopted by, this notice (Issues and Decision Memo).

<sup>4</sup> The regulation that was in effect when SGBC/SKF requested revocation was amended in 1997 to become 19 CFR 351.222(b). This regulation was then revoked in 2012. See *Modification to Regulation Concerning the Revocation of Antidumping and Countervailing Duty Orders*, 77 FR 29875 (May 21, 2012). However, when revoking this regulation, the Department noted that “[a]ny company that has been revoked from an antidumping . . . order will remain subject to its certified agreement to be reinstated with respect to that order if the Department finds it to have resumed dumping . . . .” See *id.* at 29882.

<sup>5</sup> See *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People’s Republic of China; Final Results of Antidumping Duty Administrative Review and Revocation in Part of Antidumping Duty Order*, 62 FR 6189 (February 11, 1997) (for the 1993–1994 review) (SGBC/SKF Revocation).

<sup>6</sup> See *SGBC/SKF Revocation*, 62 FR at 6214.

reinstated in the antidumping duty order on TRBs from the PRC effective upon the publication of this notice in the **Federal Register**. We will instruct U.S. Customs and Border Protection (CBP) to collect a cash deposit equal to the margin listed above on all entries of subject merchandise manufactured and exported by SGBC/SKF that are entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice. This deposit requirement, when imposed, shall remain in effect until further notice.

#### Notifications to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results of review in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216.

Dated: January 10, 2017.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

#### Appendix I

##### List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Margin Calculations
5. Discussion of the Issues
  - a. Factor Reporting Methodology
  - b. Surrogate Value for Truck Freight
  - c. Ministerial Errors
  - d. Adjustment to Inland Freight for Subcontracted Parts
  - e. Differential Pricing Analysis
6. Recommendation

[FR Doc. 2017-00826 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-DS-P**

#### DEPARTMENT OF COMMERCE

##### National Institute of Standards and Technology

##### Visiting Committee on Advanced Technology

**AGENCY:** National Institute of Standards and Technology, Department of Commerce.

**ACTION:** Notice of public meeting; correction.

**SUMMARY:** The National Institute of Standards and Technology (NIST) originally published a document announcing an upcoming meeting of the Visiting Committee on Advanced Technology (VCAT or Committee) on January 3, 2017 (82 FR 92). The meeting time, dates, and details have been updated. The VCAT will now meet by webinar in an open session on Wednesday, February 8, 2017 from 1:30 p.m. to 4:30 p.m. Eastern Time. The VCAT is composed of fifteen members appointed by the NIST Director who are eminent in such fields as business, research, new product development, engineering, labor, education, management consulting, environment, and international relations.

**DATES:** The VCAT will meet by webinar on Wednesday, February 8, 2017, from 1:30 p.m. to 4:30 p.m. Eastern Time.

**ADDRESSES:** The meeting will be conducted by webinar. Please note instructions under the **SUPPLEMENTARY INFORMATION** section of this notice for participation.

#### FOR FURTHER INFORMATION CONTACT:

Serena Martinez, VCAT, NIST, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, Maryland 20899-1060, telephone number 301-975-2661. Mrs. Martinez's email address is [serena.martinez@nist.gov](mailto:serena.martinez@nist.gov).

#### SUPPLEMENTARY INFORMATION:

**Authority:** 15 U.S.C. 278 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

The purpose of this meeting is for the VCAT to review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs within the framework of applicable national policies as set forth by the President and the Congress. The agenda will include an update on NIST, to include safety, and a discussion on future VCAT meeting topics and structure. NIST will also provide a brief update on the Administration and Congressional Landscape. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST Web site at <http://www.nist.gov/director/vcat/agenda.cfm>.

Members of the public can listen to the discussion by using a toll-free call-in number. When you register by email to Mrs. Serena Martinez, [serena.martinez@nist.gov](mailto:serena.martinez@nist.gov), with your name, organization affiliated with (if any), and email address, the toll-free call-in information, including passcode, will be provided to you. Callers can expect to incur regular charges for calls they initiate over wireless lines,

according to their wireless plan. The Committee will not refund any incurred charges. Callers will incur no charges for calls they initiate over land-line connections to the toll-free call-in number. Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda by email to [Stephanie.shaw@nist.gov](mailto:Stephanie.shaw@nist.gov), no later than January 31, 2017 by 5:00 p.m. Eastern Time. Approximately one-half hour will be reserved for public comments and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. The exact time for public comments will be included in the final agenda that will be posted on the NIST Web site at <http://www.nist.gov/director/vcat/agenda.cfm>. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, and those who had wished to speak but could not be accommodated on the agenda are invited to submit written statements to VCAT, NIST, 100 Bureau Drive, MS 1060, Gaithersburg, Maryland, 20899, via fax at 301-216-0529 or electronically by email to [stephanie.shaw@nist.gov](mailto:stephanie.shaw@nist.gov).

**Kevin Kimball,**

*NIST Chief of Staff.*

[FR Doc. 2017-00756 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-13-P**

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

**RIN 0648-XF158**

##### Endangered Species; File No. 19508

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that Katherine Mansfield, Ph.D., University of Central Florida, 4000 Central Florida Boulevard, Building 20, BIO301, Orlando, FL 32825, has applied in due form for a permit to take loggerhead (*Caretta caretta*), Kemp's ridley (*Lepidochelys kempii*), green (*Chelonia mydas*), hawksbill (*Eretmochelys imbricata*) and leatherback (*Dermochelys coraicea*) sea turtles for purposes of scientific research.

**DATES:** Written, telefaxed, or email comments must be received on or before February 16, 2017.

**ADDRESSES:** The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 19508 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713-0376, or by email to [NMFS.Pr1Comments@noaa.gov](mailto:NMFS.Pr1Comments@noaa.gov). Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Carrie Hubbard or Amy Hapeman, (301) 427-8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

The applicant requests a five-year permit to examine patterns and trends in the abundance, distribution, movements, foraging ecology, and population structure of sea turtles. Research would occur in three study areas: (1) Indian River Lagoon, Florida; (2) Trident Turning Basin, Cape Canaveral, Florida; and (3) Northern and Eastern Gulf of Mexico, which includes waters up to 120 miles offshore from Louisiana to Western Florida. Researchers would capture sea turtles by tangle net, dip net, or by hand; annual requested take numbers per species vary by year and project. Sea turtles would have the following procedures performed before release: Measure, flipper tag, passive integrated transponder tag, photograph/video, gastric lavage, and scute, blood, fecal, and tissue sampling. A subset of

animals would receive an epoxy-attached transmitter before release.

Dated: January 10, 2017.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2017-00811 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XF163**

#### North Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The North Pacific Fishery Management Council's (Council) Scallop Plan Team will meet February 22, 2017.

**DATES:** The meeting will be held on Wednesday, February 22, 2017, from 9 a.m. to 5 p.m.

**ADDRESSES:** The meeting will be held at Fishermen's Hall, 403 Marine Way, Kodiak, AK 99615.

*Council address:* North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501-2252; telephone: (907) 271-2809.

**FOR FURTHER INFORMATION CONTACT:** Jim Armstrong, Council staff; telephone: (907) 271-2809.

#### SUPPLEMENTARY INFORMATION:

##### Agenda

*Wednesday, February 22, 2017*

The agenda includes updating the status of the Statewide Scallop Stocks and Stock Assessment and Fishery Evaluation (SAFE) compilation, update on monitoring ocean acidification and its potential effect on the scallop stocks, update on new scallop assessment programs and a review of research priorities. The Agenda is subject to change, and the latest version will be posted at <http://www.npfmc.org/>

##### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271-2809 at least 7 working days prior to the meeting date.

Dated: January 11, 2017.

**Jeffrey N. Lonergan,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017-00887 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XF086**

#### Atlantic Highly Migratory Species; Exempted Fishing Permits

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

**ACTION:** Notice of receipt of an application for an exempted fishing permit; availability of a draft environmental assessment; request for comments.

**SUMMARY:** NMFS announces the receipt of an application for an exempted fishing permit (EFP) from Dr. David Kerstetter of Nova Southeastern University to evaluate pelagic longline (PLL) catch and bycatch rates from within two different sub-areas in the northern portion of the East Florida Coast Pelagic Longline (PLL) Closed Area (north and south of 29°50' N. lat.) and compare those rates to rates obtained by authorized samplers from outside the EFC PLL Closed Area and the availability of a draft Environmental Assessment (EA) analyzing the impacts of granting the application to conduct the research using commercial PLL vessels, with certain terms and conditions. The overall purpose of the research project would be to evaluate PLL catches and catch rates of target and non-target species within a portion of the EFC PLL Closed Area to evaluate the effectiveness of existing area closures at meeting current conservation and management goals under current conditions using standardized PLL gear on a specified number of commercial vessels.

**DATES:** Written comments on the issuance of the EFP or on the draft EA will be considered by NMFS and must be received on or before February 16, 2017.

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Email:* [nmfs.hms.pllefp@noaa.gov](mailto:nmfs.hms.pllefp@noaa.gov). Include in the subject line the following identifier: 0648-XF086.



• *Mail:* Margo Schulze-Haugen, Highly Migratory Species Management Division (F/SF1), NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** Craig Cockrell at (301) 427–8503 or Rick Pearson at (727) 824–5399.

**SUPPLEMENTARY INFORMATION:** NMFS published a notice of intent to issue EFPs, Scientific Research Permits, Letters of Acknowledgement, and Chartering Permits for Atlantic highly migratory species (HMS) in 2017 (81 FR 80646, November 16, 2016). Although that notice anticipated a variety of applications, it also stated that occasionally, NMFS receives applications for research activities that were not anticipated, or for research that is outside the scope of general scientific sampling and tagging of Atlantic HMS, or rarely, for research that is particularly controversial and that NMFS will provide additional opportunity for public comment, consistent with the regulations at 50 CFR 600.745 if that were to occur.

As discussed in the November 2016 notice of intent to issue EFPs and related permits, issuance of EFPs and related permits are necessary because HMS regulations (*e.g.*, fishing seasons, prohibited species, authorized gear, closed areas, and minimum sizes) may otherwise prohibit activities that could be undertaken for scientific data collection or other valuable purposes. Thus, pursuant to 50 CFR parts 600 and 635, a NMFS Regional Administrator or Director may issue permits to authorize, for limited testing, public display, data collection, exploratory fishing, compensation fishing, conservation engineering, health and safety surveys, environmental cleanup, and/or hazard removal purposes, the target or incidental harvest of species managed under an FMP or fishery regulations that would otherwise be prohibited. These permits exempt permit holders from the specific portions of the regulations (*e.g.*, fishing seasons, prohibited species, authorized gear, closed areas, and minimum sizes) that may otherwise prohibit the collection of HMS for public education, public display, or scientific research. The terms and conditions of individual permits are unique. EFPs and related permits are issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*) and/or the Atlantic Tunas Convention Act (ATCA) (16 U.S.C. 971 *et seq.*).

NMFS closed the EFC area to PLL gear year-round in early 2001 (65 FR 47213,

August 1, 2000). The closure was implemented to reduce bycatch and incidental catch of overfished and protected species by PLL fishermen who target HMS because there was a noticeable difference in the bycatch of some non-target species (mainly undersized swordfish) between the EFC area and open areas. At the time, Atlantic blue marlin, white marlin, sailfish, bluefin tuna, and swordfish were overfished, and bycatch reduction was a component of rebuilding efforts. In particular, the United States was implementing a 1999 swordfish rebuilding plan, and the closure helped reduce bycatch of undersized swordfish. Several other laws required that NMFS address bycatch in the HMS fisheries, including the Endangered Species Act (ESA), which required reductions in sea turtle bycatch in the PLL fishery. National Standard 9 of the MSA also requires that fishery management plans minimize bycatch and bycatch mortality to the extent practicable.

The closure has been in place for more than 15 years and, since 2001, a number of changes in stock status and fishery management measures have occurred. Specifically, North Atlantic swordfish has been rebuilt since 2009, current international assessments of white marlin and Western Atlantic sailfish indicate that overfishing is likely not occurring, the PLL fishery has been required since 2004 to use circle hooks instead of J-hooks to reduce sea turtle bycatch, and individual bluefin tuna quota (IBQ) allocations were implemented in the PLL fishery through Amendment 7 to the 2006 Consolidated HMS Fishery Management Plan in 2014 (79 FR 71509, December 2, 2014). Allowing limited access to the EFC PLL Closed Area for research purposes via an EFP would provide important data from the closed area under these changed conditions. NMFS has not obtained scientific data related to catch and bycatch rates from this area since 2010, and that data suggested that more research was needed due to the small sample size and poor spatial distribution of PLL sets in the research conducted from 2008–2010. The data resulting from the research under this EFP would be used to assess current bycatch rates during typical commercial fishing operations and to evaluate the effectiveness of the closed area in continuing to reduce bycatch of non-target species (*e.g.*, billfish, undersized swordfish, prohibited species, and protected species). It would also provide more current data about the socio-economic impact of reduced catches of target species (swordfish and tunas) as

a result of the closure, assess changes in species availability and distribution over time, and contribute to future stock assessments or other fishery management measures. Among the purposes of EFPs in the regulations are the “conduct of scientific research, the acquisition of information and data . . . , [and] the investigation of bycatch, economic discard and regulatory discard,” and such an EFP would be in furtherance of those purposes (§ 635.32(a)(1)).

NMFS received an application to conduct research within two portions of the EFC PLL Closed Area and one portion of the open area (for comparative purposes) and has made a preliminary determination that it warrants further consideration and an opportunity for public comment. The application is available for review on the HMS Management Division’s Web site at <http://www.nmfs.noaa.gov/sfa/hms/compliance/efp/index.html>. The research conducted within the EFC PLL Closed Area and in the open areas would be carried out by no more than six PLL vessels at any one time. An additional seven “backup” vessels could be used to conduct research as replacements if any mechanical or technical issues arise on the other six vessels. The proposed research project would be authorized for 12 months and, pending annual review of any changed environmental conditions or impacts and of catches and catch rates of all species, as well as individual vessel performance, may be re-authorized for two additional 12-month periods. A maximum of 1,080 sets per year (12 months) would be authorized to occur between the six vessels, and sets would be distributed evenly between two sub-areas of the EFC PLL Closed Area and one open area. Each set would consist of a maximum of 750 16/0 or larger circle hooks.

NMFS invites comment on certain terms and conditions that we believe would be appropriate for inclusion on this EFP, if issued. The commercial vessels that would be participating in this EFP project are otherwise authorized to fish and, absent this EFP, would be conducting normal PLL fishing operations in open areas consistent with their past practices. NMFS conducted an analysis that compared projected catches if vessels were to continue fishing only in open areas (*i.e.*, all effort in open areas) versus projected catches from fishing operations under the EFP (*i.e.*,  $\frac{2}{3}$  effort in closed area and  $\frac{1}{3}$  effort in open area). The analysis indicated that fishing operations under the EFP could result in comparatively higher interactions with



dusky, silky, and night sharks. Many of the proposed terms and conditions are structured to maximize the survival of these shark species and to increase the Agency's understanding of these data poor stocks. The proposed terms and conditions include:

- During the proposed research project, 33 percent of sets occurring in both portions of the EFC PLL Closed Area and in open areas would be observed by NMFS-trained NOVA Southeastern University students or NMFS-approved observers.

- NMFS would review 100 percent of electronic monitoring data for sets occurring in both portions of the EFC PLL Closed Area and in open areas.

- After three dusky sharks are discarded dead by a vessel participating in the EFP, that vessel would be required to reduce the soak time of the gear to no longer than 10 hours when conducting fishing operations under the EFP. If, after reducing the soak time to no longer than 10 hours, an additional three dusky sharks are discarded dead, then that vessel would no longer be authorized to fish in the EFC PLL Closed Area under this EFP, if issued, for the remainder of the 12-month project period, unless otherwise permitted by NMFS.

- All live sharks caught but not being retained must be safely sampled (*e.g.*, fin clip) and photographed without removing the shark from the water. All fin clips and photographs would be sent to the Southeast Fisheries Science Center (SEFSC) for identification purposes.

- All sharks that are dead at haul back, including prohibited species, and all sharks being retained for sale must be biologically sampled (*e.g.*, vertebra and reproductive organs removed) to facilitate species identification and collection of life history information. All biological samples would be sent to the SEFSC.

- Sets inside and outside of the closed areas would be equipped with hook timers, in accordance with protocols established by NMFS, to determine when animals were captured and when mortality occurs.

#### Availability of a Draft Environmental Assessment

NMFS is also announcing the availability of a draft EA that analyzes the potential impacts to the human environment of granting this EFP application for experimental PLL fishing within northern portions of the EFC PLL Closed Area and one area outside the Closed Area, as the request is described above. Among other analyzed impacts, the draft EA projects the annual catches

of all HMS species, as well as some non-HMS species interactions, from the EFC PLL Closed Area and open areas that could be expected to occur if this EFP is approved. Additionally, the draft EA describes NMFS' rationale for the preferred alternative and other alternatives under consideration for this research. The draft EA may be found on the HMS Management Division's Web site at <http://www.nmfs.noaa.gov/sfa/hms/compliance/efp/index.html>. Comments on the draft EA may be submitted via the methods outlined in the ADDRESSES section of this notice.

**Authority:** 16 U.S.C. 971 *et seq.* and 16 U.S.C. 1801 *et seq.*

Dated: January 10, 2017.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017-00791 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XF153**

#### Marine Mammals; File No. 20043

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that Whitlow Au, Ph.D., University of Hawaii, P.O. Box 1346, Kaneohe, HI 96744, has applied in due form for a permit to conduct research on marine mammals in Hawaii.

**DATES:** Written, telefaxed, or email comments must be received on or before February 16, 2017.

**ADDRESSES:** The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 20043 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may

also be submitted by facsimile to (301) 713-0376, or by email to [NMFS.Pr1Comments@noaa.gov](mailto:NMFS.Pr1Comments@noaa.gov). Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Sara Young or Carrie Hubbard, (301) 427-8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222-226).

The applicant requests a five-year permit to investigate the population dynamics and behavior of cetaceans around Hawaii and the Pacific, to study: (1) The behavior and use of the acoustic environment by large whales, and (2) the effects of noise on behavior of cetaceans around Hawaii. The applicant proposes to use genetic sampling, suction-cup acoustic recording tags, high frequency pinger tags, biopsy sampling, darted satellite tags, acoustic recording, underwater video recording, behavioral observation, photo-identification, and acoustic playbacks. Target species would be: Blainville's beaked whale (*Mesoplodon densirostris*), Cuvier's beaked whale (*Ziphius cavirostris*), killer whale (*Orcinus orca*), humpback whale (*Megaptera novaeangliae*), dwarf sperm whale (*Kogia sima*), pygmy sperm whale (*K. breviceps*), short-finned pilot whale (*Globicephala macrorhynchus*), false killer whale (*Pseudorca crassidens*), pygmy killer whale (*Feresa attenuata*), melon-headed whale (*Peponocephala electra*), short-beaked common dolphin (*D. delphis*), striped dolphin (*Stenella coeruleoalba*), spinner dolphin (*S. longirostris*), pantropical spotted dolphin (*S. attenuata*), bottlenose dolphin (*Turisiops truncatus*), Risso's dolphin (*Grampus griseus*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), and rough-toothed dolphin (*Steno bredanensis*).

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial

determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: January 11, 2017.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2017-00802 Filed 1-13-17; 8:45 am]

BILLING CODE 3510-22-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XF117

#### Pacific Fishery Management Council; Public Meetings and Hearings

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

**ACTION:** Notice of opportunities to submit public comments.

**SUMMARY:** The Pacific Fishery Management Council (Pacific Council) has announced its annual preseason management process for the 2017 ocean salmon fisheries. This notice informs the public of opportunities to provide comments on the 2017 ocean salmon management measures.

**DATES:** Written comments on the salmon management alternatives adopted by the Pacific Council at its March 2017 meeting, and described in Preseason Report II, received electronically or in hard copy by 5:00 p.m. Pacific Time, March 31, 2017, will be considered in the Pacific Council's final recommendation for the 2017 management measures.

**ADDRESSES:** Documents will be available from Mr. Herb Pollard, Chair, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384, and posted on the Pacific Council Web site at <http://www.pcouncil.org>. You may submit comments, identified by NOAA-NMFS-2016-0160, by any one of the following methods:

- **Electronic Submissions:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <http://www.regulations.gov/>

*#/docketDetail;D=NOAA-NMFS-2016-0160*, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- **Mail:** Mr. Herb Pollard, Chair, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

- **Fax:** 503-820-2299, Attn: Ms. Robin Ehlke.

- Comments can also be submitted via email to [PFMC.comments@noaa.gov](mailto:PFMC.comments@noaa.gov).

**Instructions:** Comments sent by any other method, to any other address or individual may not be considered by NMFS or the Pacific Council. All comments received are a part of the public record and will generally be posted for public viewing on <http://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS and the Pacific Council will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

**FOR FURTHER INFORMATION CONTACT:** Ms. Robin Ehlke, Pacific Council, telephone: 503-820-2280. For information on submitting comments via the Federal e-Rulemaking portal, contact Peggy Mundy, NMFS West Coast Region, telephone: 206-526-4323; email: [peggy.mundy@noaa.gov](mailto:peggy.mundy@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The Pacific Council has published its annual notice of availability of reports, public meetings, and hearings for the 2017 ocean salmon fisheries (81 FR 95568, December 28, 2016). The Pacific Council will adopt alternatives for 2017 ocean salmon fisheries at its meeting, March 7-14, 2017, at the Hilton in Vancouver, WA. Details of this meeting are available on the Pacific Council's Web site (<http://www.pcouncil.org>) and will be published in the **Federal Register** in February 2017. On March 22, 2017, "Preseason Report II—Proposed Alternatives and Environmental Assessment Part 2 for 2017 Ocean Salmon Fishery Regulations" is scheduled to be posted on the Pacific Council Web site at <http://www.pcouncil.org>. The report will include a description of the salmon management alternatives and a summary of their biological and economic impacts. Public hearings will be held to receive comments on the proposed ocean salmon fishery management alternatives adopted by the Pacific Council. Written comments received at the public hearings and a

summary of oral comments at the hearings will be provided to the Pacific Council at its April meeting.

All public hearings begin at 7 p.m. at the following locations:

- March 27, 2017: Chateau Westport, Beach Room, 710 West Hancock, Westport, WA 98595, telephone 360-268-9101.

- March 27, 2017: Red Lion Hotel, South Umpqua Room, 1313 North Bayshore Drive, Coos Bay, OR 97420, telephone 541-267-4141.

- March 28, 2017: City of Fort Bragg, Town Hall, 363 North Main Street, Fort Bragg, CA 95437, telephone: (707) 961-2823.

Comments on the alternatives the Pacific Council adopts at its March 2017 meeting, and described in Preseason Report II, may be submitted in writing or electronically as described under **ADDRESSES**, or verbally or in writing at any of the public hearings held on March 27-28, 2017, or at the Pacific Council's meeting, April 6-12, 2017, at the DoubleTree by Hilton, in Sacramento, CA. Details of these meetings will be available on the Pacific Council's Web site (<http://www.pcouncil.org>) and will be published in the **Federal Register**. Written and electronically submitted comments must be received no later than 5:00 p.m. Pacific Time, March 31, 2017, in order to be included in the briefing book for the April Council meeting where they will be considered in the adoption of the Pacific Council's final recommendation for the 2017 ocean salmon fishery management measures. All comments received accordingly will be reviewed and considered by the Pacific Council and NMFS.

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

Dated: January 10, 2017.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017-00801 Filed 1-13-17; 8:45 am]

BILLING CODE 3510-22-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Proposed Information Collection; Comment Request; Atlantic Sea Scallops Amendment 10 Data Collection

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before March 20, 2017.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at [JJessup@doc.gov](mailto:JJessup@doc.gov)).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to Shannah Jaburek, (978) 282-8456 or [Shannah.Jaburek@noaa.gov](mailto:Shannah.Jaburek@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

This request is for an extension of a currently approved information collection.

The National Marine Fisheries Service (NMFS) Greater Atlantic Region manages the Atlantic sea scallop (scallop) fishery of the Exclusive Economic Zone (EEZ) off the East Coast under the Atlantic Sea Scallop Fishery Management Plan (FMP). The regulations implementing the FMP are at 50 CFR part 648. To successfully implement and administer components of the FMP, OMB Control No. 0648-0491 includes the following information collections for scallop vessel owners, operators, and fishery participants: Vessel monitoring system (VMS) trip declarations for all scallop vessels, including powerdown declarations; notification of access area trip termination for limited access scallop vessels; submission of access area compensation trip identification; submission of access area trip exchange forms; VMS purchase and installation for individuals that purchase a federally permitted scallop vessel; VMS daily catch reports; submission of ownership cap forms for individual fishing quota (IFQ) scallop vessels; submission of vessel replacement, upgrade and permit history applications for IFQ, Northern Gulf of Maine (NGOM), and Incidental Catch (IC) scallop vessels; submission of VMS pre-landing notification form by IFQ vessels and limited access vessels for access areas; enrollment into the state waters exemption program; submission of requests for IFQ transfers; payment of cost recovery bills for IFQ

vessels; sector proposals for IFQ vessels and industry participants; and sector operations plans for approved sector proposals.

Data collected through these programs are incorporated into the NMFS database and are used to track and confirm vessel permit status and eligibility, scallop landings, and scallop vessel allocations. Aggregated summaries of the collected information will be used to evaluate the management program and future management proposals.

**II. Method of Collection**

Participants will submit electronic VMS transmissions and paper applications by mail, facsimile, or email.

**III. Data**

*OMB Number:* 0648-0491.

*Form Number:* None.

*Type of Review:* Regular submission (extension of a currently approved collection).

*Affected Public:* Business or other for-profits organizations.

*Estimated Number of Respondents:* 647.

*Estimated Time per Response:* VMS trip declaration, trip termination, compensation trip identification, powerdown provision, daily catch reports, 2 minutes; access area trip exchange, 15 minutes; VMS purchase and installation, 2 hours; IFQ ownership cap forms, 5 minutes; vessel replacement, upgrade and permit history applications, 3 hours; VMS pre-landing notification form, 5 minutes; VMS state waters exemption program, 2 minutes; quota transfers, 10 minutes; cost recovery, 2 hours; sector proposals, 150 hours; sector operations plans, 100 hours; IFQ, Northern Gulf of Maine, and incidental catch vessel VMS requirements, 2 minutes.

*Estimated Total Annual Burden Hours:* 3,460.

*Estimated Total Annual Cost to Public:* \$790,283.

**IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 11, 2017.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2017-00816 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**RIN 0648-XF154**

**Marine Mammals; File Nos. 19703 and 20993**

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

**ACTION:** Notice; receipt of applications.

**SUMMARY:** Notice is hereby given that Fred Sharpe, Ph.D., Alaska Whale Foundation, 4739 University Way NE., #1230, Seattle, WA 98105 (File No. 19703) has applied in due form for a permit to conduct research on cetaceans and Christopher Cilfone, Be Blue, 2569 Douglas Hwy. Unit 1, Juneau, AK 99801 (File No. 20993) has applied in due form to conduct commercial/educational photography on humpback whales (*Megaptera novaeangliae*).

**DATES:** Written, telefaxed, or email comments must be received on or before February 16, 2017.

**ADDRESSES:** The application and related documents for File No. 19703 are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 19703 from the list of available applications.

Documents for File No. 19703 and 20993 are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on these applications should be submitted to the Chief, Permits and Conservation Division, at the address listed above.

Comments may also be submitted by facsimile to (301) 713-0376, or by email to [NMFS.Pr1Comments@noaa.gov](mailto:NMFS.Pr1Comments@noaa.gov). Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on the application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:**

Carrie Hubard or Shasta McClenahan, (301) 427-8401.

**SUPPLEMENTARY INFORMATION:** The subject permits are requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222-226).

Dr. Sharpe (File No. 19703) proposes to study humpback and killer (*Orcinus orca*) whales in Alaska using both vessel and aerial surveys and a variety of methods including photo-identification, passive and active acoustics, underwater video/photography, unmanned aircraft systems, prey mapping, and suction-cup tagging. The purpose of the research is to continue a long-term study of the behavior of Alaskan humpback whales, focusing on social structure, vocalizations, and feeding. Forty harbor porpoises (*Phocoena phocoena*), 50 Dall's porpoises (*Phocoenoides dalli*), 130 harbor seals (*Phoca vitulina*), and 80 Steller sea lions (*Eumetopias jubatus*) may be incidentally harassed during research activities. The permit would be valid for five years.

Mr. Cilfone (File No. 20993) proposes to film humpback whales in Hawaiian waters of the Maui Nui Basin. Footage would be used to create a film about humpback whales and their conservation success that would be available on multiple platforms. Boats, unmanned aircraft systems, pole cameras, and snorkelers would all be used to get footage. Fifty humpback whales would be approached annually. In addition, pantropical spotted (*Stenella attenuata*), spinner (*S. longirostris*), and bottlenose (*Tursiops truncatus*) dolphins may be incidentally harassed during filming operations. Filming would occur in winter and spring and the permit would be valid until May 2017.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the applications to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: January 10, 2017.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2017-00807 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XF161

#### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Tilefish Advisory Panel of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

**DATES:** The meeting will be held on Thursday, February 9, 2017, beginning at 9 a.m. and conclude by 12 noon. For agenda details, see **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** The meeting will be held via webinar with a telephone-only connection option: <http://mafmc.adobeconnect.com/tile-ap-2017/>.

**Council address:** Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331 or on their Web site at [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to create a fishery performance report by the Council's Tilefish Advisory Panel. The intent of this report is to facilitate a venue for structured input from the Advisory Panel members for the Golden

and BlueLine Tilefish specifications process, including recommendations by the Council and its Scientific and Statistical Committee (SSC).

#### Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: January 11, 2017.

**Jeffrey N. Lonergan,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017-00818 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Telecommunications and Information Administration

#### Multistakeholder Process on Internet of Things Security Upgradability and Patching

**AGENCY:** National Telecommunications and Information Administration, U.S. Department of Commerce.

**ACTION:** Notice of open meeting.

**SUMMARY:** The National Telecommunications and Information Administration (NTIA) will convene a virtual meeting of a multistakeholder process concerning Internet of Things Security Upgradability and Patching on January 31, 2017.

**DATES:** The meeting will be held on January 31, 2017, from 2:00 p.m. to 4:30 p.m., Eastern Time.

**ADDRESSES:** This is a virtual meeting. NTIA will post links to online content and dial-in information on the multistakeholder process Web site at <https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>.

**FOR FURTHER INFORMATION CONTACT:** Allan Friedman, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone: (202) 482-4281; email: [afriedman@ntia.doc.gov](mailto:afriedman@ntia.doc.gov). Please direct media inquiries to NTIA's Office of Public Affairs: (202) 482-7002; email: [press@ntia.doc.gov](mailto:press@ntia.doc.gov).

**SUPPLEMENTARY INFORMATION:** **Background:** In March of 2015 the National Telecommunications and Information Administration issued a Request for Comment to "identify substantive cybersecurity issues that

affect the digital ecosystem and digital economic growth where broad consensus, coordinated action, and the development of best practices could substantially improve security for organizations and consumers.”<sup>1</sup> We received comments from a range of stakeholders, including trade associations, large companies, cybersecurity startups, civil society organizations and independent computer security experts.<sup>2</sup> The comments recommended a diverse set of issues that might be addressed through the multistakeholder process, including cybersecurity policy and practice in the emerging area of Internet of Things (IoT). On August 2, 2016, NTIA announced that it would convene a new multistakeholder process on security upgradability and patching for consumer IoT.<sup>3</sup> NTIA subsequently announced that the first meeting of this process would be held on October 19, 2016.<sup>4</sup>

The matter of patching vulnerable systems is now an accepted part of cybersecurity.<sup>5</sup> Unaddressed technical flaws in systems leave the users of software and systems at risk. The nature of these risks varies, and mitigating these risks requires various efforts from the developers and owners of these systems. One of the more common means of mitigation is for the developer or other maintaining party to issue a security patch to address the vulnerability. Patching has become more commonly accepted, even for consumers, as more operating systems and applications shift to visible reminders and automated updates. Yet as one security expert notes, this evolution of the software industry has

yet to become the dominant model in IoT.<sup>6</sup>

To help realize the full innovative potential of IoT, users need reasonable assurance that connected devices, embedded systems, and their applications will be secure. A key part of that security is the mitigation of potential security vulnerabilities in IoT devices or applications through patching and security upgrades.

The ultimate objective of the multistakeholder process is to foster a market offering more devices and systems that support security upgrades through increased consumer awareness and understanding. Enabling a thriving market for patchable IoT requires common definitions so that manufacturers and solution providers have shared visions for security, and consumers know what they are purchasing. Currently, no such common, widely accepted definitions exist, so many manufacturers struggle to effectively communicate to consumers the security features of their devices. This is detrimental to the digital ecosystem as a whole, as it does not reward companies that invest in patching, and it prevents consumers from making informed purchasing choices.

At the October 19, 2016, meeting, stakeholders discussed the challenge of patching, and how to scope the discussion. Participants identified five distinct work streams that could help foster better security across the ecosystem, and established working groups to more fully evaluate options in each of these areas.<sup>7</sup> The main objective of the January 31, 2016, meeting is to share progress from the working groups examining the five work streams, and hear feedback from the broader stakeholder community. Stakeholders will also discuss overall progress on the initiative, and identify any additional work that may be needed.

More information about stakeholder work will be available at: <https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>.

**Time and Date:** NTIA will convene a virtual meeting of the multistakeholder process on IoT Security Upgradability and Patching on January 31, 2017, from 2:00 p.m. to 4:30 p.m., Eastern Time. Please refer to NTIA’s Web site, <https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>.

<sup>6</sup> Bruce Schneier, *The Internet of Things Is Wildly Insecure—And Often Unpatchable*, Wired (Jan. 6, 2014) available at: [https://www.schneier.com/blog/archives/2014/01/security\\_risks\\_9.html](https://www.schneier.com/blog/archives/2014/01/security_risks_9.html).

<sup>7</sup> See NTIA, Multistakeholder Process; Internet of Things (IoT) Security Upgradability and Patching, at: <https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>.

[www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security](https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security), for the most current information.

**Place:** This is a virtual meeting. NTIA will post links to online content and dial-in information on the multistakeholder process Web site at <https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>.

**Other Information:** The meeting is open to the public and the press. There will be an opportunity for stakeholders viewing the webcast to participate remotely in the meetings through a moderated conference bridge, including polling functionality. Access details for the meetings are subject to change. Requests for a transcript of the meeting or other auxiliary aids should be directed to Allan Friedman at (202) 482-4281 or [afriedman@ntia.doc.gov](mailto:afriedman@ntia.doc.gov) at least seven (7) business days prior to each meeting. Please refer to NTIA’s Web site, <http://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security>, for the most current information.

Dated: January 11, 2017.

**Kathy D. Smith,**

*Chief, National Telecommunications and Information Administration.*

[FR Doc. 2017-00817 Filed 1-13-17; 8:45 am]

**BILLING CODE 3510-60-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Charter Amendment of Department of Defense Federal Advisory Committees

**AGENCY:** Department of Defense.

**ACTION:** Amendment of Federal Advisory Committee.

**SUMMARY:** The Department of Defense (DoD) is publishing this notice to announce that it is amending the charter for the Advisory Committee on Arlington National Cemetery.

**FOR FURTHER INFORMATION CONTACT:** Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703-692-5952.

**SUPPLEMENTARY INFORMATION:** This committee’s charter is being amended in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102-3.50(d). The amended charter and contact information for the Committee’s Designated Federal Officer (DFO) can be obtained at <http://www.facadatabase.gov/>.

The DoD is amending the charter for the Advisory Committee on Arlington

<sup>1</sup> U.S. Department of Commerce, Internet Policy Task Force, Request for Public Comment, Stakeholder Engagement on Cybersecurity in the Digital Ecosystem, 80 FR 14360, Docket No. 150312253-5253-01 (Mar. 19, 2015), available at: [https://www.ntia.doc.gov/files/ntia/publications/cybersecurity\\_rfc\\_03192015.pdf](https://www.ntia.doc.gov/files/ntia/publications/cybersecurity_rfc_03192015.pdf).

<sup>2</sup> NTIA has posted the public comments received at <https://www.ntia.doc.gov/federal-register-notice/2015/comments-stakeholder-engagement-cybersecurity-digital-ecosystem>.

<sup>3</sup> NTIA, Increasing the Potential of IoT through Security and Transparency (Aug. 2, 2016), available at: <https://www.ntia.doc.gov/blog/2016/increasing-potential-iot-through-security-and-transparency>.

<sup>4</sup> NTIA, Notice of Multistakeholder Process on Internet of Things Security Upgradability and Patching Open Meeting (Sept. 15, 2016), available at: <https://www.ntia.doc.gov/federal-register-notice/2016/10192016-meeting-notice-msp-iot-security-upgradability-patching>.

<sup>5</sup> See, e.g., Murugiah Souppaya and Karen Scarfone, *Guide to Enterprise Patch Management Technologies, Special Publication 800-40 Revision 3*, National Institute of Standards and Technology, NIST SP 800-40 (2013) available at: <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-40r3.pdf>.

National Cemetery (“the Committee”) previously published in the **Federal Register** on July 26, 2016 (81 FR 48763). The Committee’s charter is being amended to update the number of permanent subcommittees to two and establish the function of the new Remember and Explore subcommittee. All other aspects of the Committee’s charter, as previously published, will apply to the Committee.

Dated: January 11, 2017.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2017–00862 Filed 1–13–17; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Termination of Department of Defense Federal Advisory Committees

**AGENCY:** Department of Defense.

**ACTION:** Termination of Federal Advisory Committee.

**SUMMARY:** The Department of Defense (DoD) is publishing this notice to announce that it is terminating the Advisory Council on Dependents’ Education.

**FOR FURTHER INFORMATION CONTACT:** Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

**SUPPLEMENTARY INFORMATION:** Section 576 of the National Defense Authorization Act for Fiscal Year 2017 (Pub. L. 114–328) rescinds 22 U.S.C. 929, which is the statutory authority for the Advisory Council on Dependents’ Education (“the Council”). Therefore, the Department of Defense is terminating the Council.

Dated: January 11, 2017.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2017–00868 Filed 1–13–17; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID DOD–2008–HA–0180]

#### Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Defense has submitted to OMB for clearance, the

following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by February 16, 2017.

**FOR FURTHER INFORMATION CONTACT:** Fred Licari, 571–372–0493.

#### **SUPPLEMENTARY INFORMATION:**

*Title, Associated Form and OMB Number:* Professional Qualifications Medical/Peer Reviewers; CHAMPUS Form 780; OMB Control Number 0720–0005.

*Type of Request:* Reinstatement.

*Number of Respondents:* 60.

*Responses per Respondent:* 1.

*Annual Responses:* 60.

*Average Burden per Response:* 20 minutes.

*Annual Burden Hours:* 20.

*Needs and Uses:* The information collection requirement is necessary to obtain and record the professional qualifications of medical and peer reviewers utilized within TRICARE®. The form is included as an exhibit in an appeal or hearing case file as evidence of the reviewer’s professional qualifications to review the medical documentation contained in the case file.

*Affected Public:* Business or other for profit.

*Frequency:* On occasion.

*Respondent’s Obligation:* Voluntary.

*OMB Desk Officer:* Ms. Stephanie Tatham.

Comments and recommendations on the proposed information collection should be emailed to Ms. Stephanie Tatham, DoD Desk Officer, at *Oira\_submission@omb.eop.gov*. Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Instructions:* All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

*DOD Clearance Officer:* Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: January 11, 2017.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2017–00829 Filed 1–13–17; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

#### Meeting of the Ocean Research Advisory Panel

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Notice of open meeting.

**SUMMARY:** The Ocean Research Advisory Panel (ORAP) will hold a regularly scheduled meeting. The meeting will be open to the public.

**DATES:** The meeting will be held on Wednesday, January 11, 2017 from 9:00 a.m. to 11:00 a.m., Eastern Time. Members of the public should submit their comments in advance of the meeting to the meeting Point of Contact. Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Ocean Research Advisory Panel was unable to provide public notification of its meeting of January 11, 2017, as required by 41 CFR 102–3.150(a). Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

**ADDRESSES:** This will be a teleconference. For access, connect to: <https://global.gotomeeting.com/join/822051381>. The call-in number will be: (312) 757–3121, with access code: 822–051–381.

**FOR FURTHER INFORMATION CONTACT:** CDR Joel W. Feldmeier, Office of Naval Research, 875 North Randolph Street Suite 1425, Arlington, VA 22203–1995, telephone 703–696–5121.

**SUPPLEMENTARY INFORMATION:** This notice of open meeting is provided in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2). The meeting will include discussions on ocean research, resource management, and other current issues in the ocean science and management communities.

Dated: January 10, 2017.

A.M. Nichols,

Lieutenant Commander, Judge Advocate  
General's Corps, U.S. Navy, Federal Register  
Liaison Officer.

[FR Doc. 2017-00812 Filed 1-13-17; 8:45 am]

BILLING CODE 3810-FF-P

## DEPARTMENT OF DEFENSE

### Department of the Navy

#### Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

**SUMMARY:** The inventions listed below are assigned to the United States Government, as represented by the Secretary of the Navy and are available for domestic and foreign licensing by the Department of the Navy.

The following patents are available for licensing: Patent No. 9,536,620 (Navy Case No. 200321): METHOD AND SYSTEM FOR IMPROVING THE RADIATION TOLERANCE OF FLOATING GATE MEMORIES// and Patent No. 9,535,562 (Navy Case No. 101979): COGNITIVE LOAD REDUCTION AND FIELD OF VIEW ENHANCING STANDARDIZED GRAPHICAL USER INTERFACE (GUI) OVERLAY GENERATING SYSTEM OR SYSTEMS THAT INCLUDE ELEMENTS THAT CORRELATE VARIOUS DEVICE, EVENT, OR OPERATION INPUTS WITH COMMON GUI OVERLAY GENERATION MODULES AND GROUP RELATED GUI ELEMENTS ACROSS OVERLAYS ALONG WITH ASSOCIATED METHODS.

**ADDRESSES:** Requests for copies of the patents cited should be directed to Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522-5001.

**FOR FURTHER INFORMATION CONTACT:** Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522-5001, Email [Christopher.Monsey@navy.mil](mailto:Christopher.Monsey@navy.mil).

**Authority:** 35 U.S.C. 207, 37 CFR part 404.

Dated: January 10, 2017.

A.M. Nichols,

Lieutenant Commander, Judge Advocate  
General's Corps, U.S. Navy, Federal Register  
Liaison Officer.

[FR Doc. 2017-00813 Filed 1-13-17; 8:45 am]

BILLING CODE 3810-FF-P

## DEPARTMENT OF ENERGY

### Nuclear Energy Advisory Committee

AGENCY: Office of Nuclear Energy,  
Department of Energy.

ACTION: Notice of open meeting.

**SUMMARY:** This notice announces a meeting of the Nuclear Energy Advisory Committee (NEAC). Federal Advisory Committee Act (Pub. L. 94-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

**DATE:** Thursday, February 16, 2017.

**TIME:** 4:00 p.m.–5:00 p.m. (EST).

**ADDRESSES:** The public teleconference will be held by teleconference only. The teleconference number is: (267) 930-4000; participation code: 580-520-181.

**FOR FURTHER INFORMATION CONTACT:** Bob Rova, Designated Federal Officer, U.S. Department of Energy, 19901 Germantown Rd, Germantown, MD 20874; telephone (301) 903-9096; email [robert.rova@nuclear.energy.gov](mailto:robert.rova@nuclear.energy.gov).

#### SUPPLEMENTARY INFORMATION:

**Background:** The Nuclear Energy Advisory Committee (NEAC), formerly the Nuclear Energy Research Advisory Committee (NERAC), was established in 1998 by the U.S. Department of Energy (DOE) to provide advice on complex scientific, technical, and policy issues that arise in the planning, managing, and implementation of DOE's civilian nuclear energy research programs. The committee is composed of 19 individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to nuclear energy.

**Purpose of the Meeting:** Discussion and approval of the NEAC report "Assessment of Missions and Requirements for a New U.S. Test Reactor".

**Tentative Agenda:** Discussion and approval of report.

**Public Participation:** Individuals and representatives of organizations are invited to listen to the meeting on February 16, 2017. The draft report is posted on NEAC's Web site: <https://energy.gov/ne/services/nuclear-energy-advisory-committee>. Comments on the report can be sent to: [NEAC@nuclear.energy.gov](mailto:NEAC@nuclear.energy.gov). Comments are due by Tuesday, January 31, 2017.

**Minutes:** The minutes of the meeting will be available by contacting Mr. Rova at the address above or on the Department of Energy, Office of Nuclear Energy Web site at <http://energy.gov/ne/services/nuclear-energy-advisory-committee>.

Issued in Washington, DC, on January 11, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017-00865 Filed 1-13-17; 8:45 am]

BILLING CODE 6450-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2013-0602; FRL-9958-45-OAR]

### Denial of Reconsideration and Administrative Stay of the Emission Guidelines for Greenhouse Gas Emissions and Compliance Times for Electric Utility Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action denying petitions for reconsideration and petitions for administrative stay.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) received 38 petitions for reconsideration of the final Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, published in the **Federal Register** on October 23, 2015. The agency is providing notice that it denied the petitions for reconsideration except to the extent they raise topics concerning biomass and waste-to-energy, and it is deferring action on the petitions to the extent they raised those topics. The EPA also received 22 petitions for an administrative stay of this rule. The agency is providing notice that it denied these petitions. The basis for the EPA's actions is set out fully in letters sent to the petitioners and a separate memorandum available in the rulemaking docket.

**DATES:** The EPA took final action to deny the petitions for reconsideration except to the extent they raised certain topics, and to deny petitions for an administrative stay, on January 11, 2017.

**FOR FURTHER INFORMATION CONTACT:** Joseph Goffman, Office of Air and Radiation (6101A), U.S. EPA, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number (202) 564-7400, facsimile number (202) 564-1408; email address: [CarbonPollutionInput@epa.gov](mailto:CarbonPollutionInput@epa.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Where can I get a copy of this document and other related information?

A copy of this **Federal Register** notice, the petitions for reconsideration,



the petitions for an administrative stay, the letters taking action on those petitions, and the separate memorandum describing the full basis for those actions will be available in the rulemaking docket (Docket ID EPA–HQ–OAR–2013–0602). In addition, following signature, an electronic copy of these documents will be available on the World Wide Web (WWW) at the following address: <https://www.epa.gov/cleanpowerplan>.

## II. Judicial Review

Section 307(b)(1) of the Clean Air Act (CAA) specifies which Federal Courts of Appeal have venue over petitions for review of final EPA actions. This section provides, in part, that “a petition for review of action of the Administrator in promulgating . . . any standard of performance or requirement under section [111] of [the CAA],” or any other “nationally applicable” final action, “may be filed only in the United States Court of Appeals for the District of Columbia.”

The EPA has determined that its actions denying the petitions for reconsideration or for an administrative stay are nationally applicable for purposes of CAA section 307(b)(1) because the action directly affects the Emission Guidelines for Greenhouse Gas Emissions and Compliance Times for Electric Utility Generating Units, which are nationally applicable CAA section 111 standards. Thus, any petitions for review of the EPA’s decision to deny petitioners’ requests for reconsideration or for an administrative stay must be filed in the United States Court of Appeals for the District of Columbia by March 20, 2017.

## III. Background and Summary of the Action

On October 23, 2015, pursuant to section 111 of the CAA, the EPA published the final rule titled “Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units.” 80 FR 64661. Following promulgation of the final emission guidelines, the Administrator received petitions for reconsideration of certain provisions of the final rule pursuant to CAA section 307(d)(7)(B) and petitions for an administrative stay under the Administrative Procedure Act (APA), 5 U.S.C. 705 and CAA section 307(d)(7)(B).

CAA section 307(d)(7)(B) requires the EPA to convene a proceeding for reconsideration of a rule if a party raising an objection to the rule “can demonstrate to the Administrator that it was impracticable to raise such objection within [the public comment

period] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.” The requirement to convene a proceeding to reconsider a rule is thus based on the petitioner demonstrating to the EPA both: (1) That it was impracticable to raise the objection during the comment period, or that the grounds for such objection arose after the comment period, but within the time specified for judicial review (*i.e.*, within 60 days after publication of the final rulemaking notice in the **Federal Register**, see CAA section 307(b)(1)); and (2) that the objection is of central relevance to the outcome of the rule.

The EPA received 38 petitions for reconsideration of the CAA section 111(d) greenhouse gas emission guidelines from the following entities: Alabama Department of Environmental Management (DEM); Ameren Corporation (Ameren); American Electric Power System (AEP); Arkansas Office of the Attorney General (Arkansas); Basin Electric Power Cooperative (Basin); Biogenic CO<sub>2</sub> Coalition; Biomass Power Association (BPA), the Energy Recovery Council (ERC) and the Local Government Coalition for Renewable Energy (LGCRC); Commonwealth of Kentucky (Kentucky); Dairyland Power Cooperative, Madison Gas and Electric Company, We Energies, Wisconsin Power and Light Company, Wisconsin Public Service Corporation, and WPPI Energy (Wisconsin utilities); Denbury Onshore, LLC (Denbury); Energy and Environment Legal Institute; ERC; Entergy; Hoosier Energy Rural Electric Cooperative, Eastern Kentucky Power Cooperative, and Minnkota Power Cooperative; Intermountain Power Agency; Kansas Department of Health and Environment (DHE); LGCRC; Louisville Gas & Electric Company (LG&E) and Kentucky Utilities Company (KU); Mississippi Department of Environmental Quality (DEQ); Mississippi Public Service Commission (PSC); National Alliance of Forest Owners (NAFO); National Association of Home Builders; National Rural Electric Cooperative Association (NRECA); Newmont Nevada Energy Investment LLC and Newmont USA Limited (Newmont); NorthWestern Energy; Oglethorpe Power Corporation (Oglethorpe); Prairie State Generating Company, LLC (Prairie State); Southern Company; State of Montana Office of the Attorney General (Montana); State of Nebraska Office of the Attorney General

and Nebraska Department of Environmental Quality (Nebraska); State of New Jersey Department of Environmental Protection (DEP); State of North Dakota Office of the Attorney General (North Dakota); State of Texas Office of the Attorney General, Texas Commission on Environmental Quality, Public Utility Commission of Texas, and the Railroad Commission of Texas (Texas); State of West Virginia Office of the Attorney General (West Virginia); State of Wisconsin, Wisconsin Department of Natural Resources, and Public Service Commission of Wisconsin (Wisconsin); State of Wyoming (Wyoming); Utility Air Regulatory Group (UARG); and Westar Energy Incorporated (Westar Energy).

In letters to petitioners, the EPA denied 31 of the petitions for reconsideration in full, and denied Kentucky’s and Oglethorpe’s petition for reconsideration except to the extent they raised the topic of biomass, as not satisfying one or both of the statutory conditions for compelled reconsideration. The EPA is deferring action on the petitions to the extent they cover the topics of biomass and waste-to-energy.<sup>1</sup> The EPA is deferring with respect to biomass pending our further on-going consideration of the underlying issue of whether and how to account for biomass when co-firing with fossil fuels.

We discuss each of the topics in the petitions we denied and the basis for those denials in a separate, docketed memorandum titled “Basis for Denial of Petitions to Reconsider and Petitions to Stay the CAA Section 111(d) Emission Guidelines for Greenhouse Gas Emissions and Compliance Times for Electric Utility Generating Units.” For reasons set out in the memorandum, the EPA denied the petitions for reconsideration for the following petitioners: Alabama DEM; Ameren; AEP; Arkansas; Basin; Kentucky<sup>2</sup>; Wisconsin utilities; Denbury; Energy and Environment Legal Institute; Entergy; Hoosier Energy Rural Electric Cooperative, Eastern Kentucky Power Cooperative, and Minnkota Power Cooperative; Intermountain Power Agency; Kansas DHE; LG&E and KU; Mississippi DEQ; Mississippi PSC; National Association of Home Builders; NRECA; Newmont; NorthWestern Energy; Oglethorpe; Prairie State; Southern Company; Montana; Nebraska;

<sup>1</sup> These topics were included in the petitions of the Biogenic CO<sub>2</sub> Coalition, Biomass Power Association, Kentucky, ERC, LGCRC, Oglethorpe, and NAFO.

<sup>2</sup> As noted, the EPA is deferring action on Kentucky’s and Oglethorpe’s petitions to the extent they raise the topic of biomass.



New Jersey DEP; North Dakota; Texas; West Virginia; Wisconsin; Wyoming; UARG; and Westar Energy.

APA section 705 provides, "When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review." 5 U.S.C. 705. Under CAA section 307(d)(7)(B), the EPA may stay the effectiveness of a rule while it is being reconsidered "for a period not to exceed three months."

The EPA received 22 petitions for an administrative stay under APA section 705 and CAA section 307(d)(7)(B).

The EPA received petitions from West Virginia and a group of 15 other states; Ameren; Basin; Business Associations; Denbury; Kansas DHE; Mississippi DEQ; Mississippi PSC; Montana; NAFO; National Mining Association; Nebraska; New Jersey DEP; North Dakota; NorthWestern Energy; Peabody Energy Corporation; Prairie State; Texas; UARG; and Westar Energy.

The EPA responded to several of these petitions by letters stating that we were not taking action on them in light of the stay imposed on the rule by the U.S. Supreme Court on February 7, 2016. Subsequently, the EPA sent letters to all the petitioners denying each of these petitions for the reasons explained in the memorandum referred to above, "Basis for Denial of Petitions to Reconsider and Petitions to Stay the CAA Section 111(d) Emission Guidelines for Greenhouse Gas Emissions and Compliance Times for Electric Utility Generating Units."

Dated: January 11, 2017.

**Gina McCarthy,**  
Administrator.

[FR Doc. 2017-00941 Filed 1-13-17; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OGC-2016-0719; FRL-9958-39-OGC]

### Proposed Consent Decree, Clean Air Act Citizen Suit

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed consent decree; request for public comment.

**SUMMARY:** In accordance with section 113(g) of the Clean Air Act, as amended ("CAA" or the "Act"), notice is hereby given of a proposed consent decree to address a lawsuit filed by the Center for Biological Diversity and the Center for Environmental Health (collectively "Plaintiffs") in the United States District

Court for the Northern District of California: *Center for Biological Diversity, et al. v. McCarthy*, No. 3:16-cv-03796-VC (N.D. Cal.). On July 7, 2016, Plaintiffs filed a complaint in this lawsuit alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency ("EPA"), failed to perform nondiscretionary duties under the CAA to complete periodic reviews of the air quality criteria and the primary National Ambient Air Quality Standards ("NAAQS") for sulfur oxides ("SO<sub>x</sub>") and the primary NAAQS for oxides of nitrogen ("NO<sub>x</sub>"), to make such revisions to those air quality criteria and NAAQS as may be appropriate, and to promulgate such new NAAQS as may be appropriate. The proposed consent decree would establish deadlines for EPA to take certain, specified actions.

**DATES:** Written comments on the proposed consent decree must be received by February 16, 2017.

**ADDRESSES:** Submit your comments, identified by Docket ID number EPA-HQ-OGC-2016-0719, online at [www.regulations.gov](http://www.regulations.gov). Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). If you would like to submit a comment using a different submission method, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Melina Williams, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564-3406; fax number: (202) 564-5603; email address: [williams.melina@epa.gov](mailto:williams.melina@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. Additional Information About the Proposed Consent Decree

Under section 109(d) of the CAA, EPA is required to periodically review air quality criteria and NAAQS and to make such revisions as may be appropriate. The proposed consent decree addresses a lawsuit filed by Plaintiffs alleging that EPA failed to timely complete certain periodic reviews for NO<sub>x</sub> and SO<sub>x</sub> by the deadline set forth in the CAA. The proposed consent decree would establish deadlines for EPA to take certain, specified actions in the periodic reviews, and if appropriate, revisions of the air quality criteria addressing human health effects of SO<sub>x</sub>, and the primary NAAQS for NO<sub>x</sub> and SO<sub>x</sub>. Under the terms of the proposed consent decree, EPA would: (1) Sign a notice setting forth its proposed decision concerning its review of the primary NAAQS for NO<sub>x</sub> no later than July 14, 2017; (2) sign a notice setting forth its final decision concerning its review of the primary NAAQS for NO<sub>x</sub> no later than April 6, 2018; (3) issue a final Integrated Science Assessment (a document containing air quality criteria) addressing human health effects of SO<sub>x</sub> no later than December 14, 2017; (4) sign a notice setting forth its proposed decision concerning its review of the primary NAAQS for SO<sub>x</sub> no later than May 25, 2018; and (5) sign a notice setting forth its final decision concerning its review of the primary NAAQS for SO<sub>x</sub> no later than January 28, 2019. See the proposed consent decree for additional details.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn, the terms of the decree will be affirmed.

### II. Additional Information About Commenting on the Proposed Consent Decree

*A. How can I get a copy of the proposed consent decree?*

The official public docket for this action (identified by Docket ID No.

EPA-HQ-OGC-2016-0719) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OEI Docket is (202) 566-1752.

An electronic version of the public docket is available through [www.regulations.gov](http://www.regulations.gov). You may use [www.regulations.gov](http://www.regulations.gov) to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search".

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at [www.regulations.gov](http://www.regulations.gov) without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

#### *B. How and to whom do I submit comments?*

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This

ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the [www.regulations.gov](http://www.regulations.gov) Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through [www.regulations.gov](http://www.regulations.gov), your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 6, 2017.

**Lorie J. Schmidt,**

*Associate General Counsel.*

[FR Doc. 2017-00942 Filed 1-13-17; 8:45 am]

**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OAR-2016-0017; FRL9958-38-OAR]**

### **California State Motor Vehicle Pollution Control Standards; Amendments to On-Highway Heavy-Duty Vehicle In-Use Compliance Program, Amendments to 2007 and Subsequent Model Year On-Highway Heavy-Duty Engines and Vehicles, and Amendments to Truck Requirements; Notice of Decision**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of decision.

**SUMMARY:** The Environmental Protection Agency ("EPA") is granting the California Air Resources Board's ("CARB's") request for a waiver of Clean Air Act preemption for its On-Highway Heavy-Duty Vehicle In-Use Compliance

program ("In-Use Regulation"). EPA is also confirming that CARB's amendments to its 2007 and Subsequent Model Year On-Highway Heavy-Duty Engines and Vehicles regulation ("2007 Amendments") and CARB's amendments to its Truck Idling requirements ("Truck Idling Amendments") are within the scope of previous waivers issued by EPA. The In-Use Regulation establishes a manufacturer-run in-use compliance program using portable emission measurement systems ("PEMS"). The 2007 Amendments specify the NO<sub>x</sub> emission standard for heavy- and medium-duty diesel engines to two significant figures and provide manufacturers the option to certify chassis-certified diesel vehicles within the phase-in compliance provisions of the 2007 and Subsequent Model Year On-Highway Heavy-Duty Engines and Vehicles regulation. The Truck Idling Amendments exempt armored cars and workover rigs (a mobile self-propelled rig used to perform remedial operations on producing oil or gas wells to restore or increase well production) from the new engine requirements of the preexisting California Truck Idling regulation. This decision is issued under the authority of the Clean Air Act ("CAA" or "the Act").

**DATES:** Petitions for review must be filed by March 20, 2017.

**ADDRESSES:** EPA has established a docket for this action under Docket ID EPA-HQ-OAR-2016-0017. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open to the public on all federal government working days from 8:30 a.m. to 4:30 p.m.; generally, it is open Monday through Friday, excluding holidays. The telephone number for the Reading Room is (202) 566-1744. The Air and Radiation Docket and Information Center's Web site is <http://www.epa.gov/oar/docket.html>. The email address for the Air and Radiation Docket is: [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov), the telephone number is (202) 566-1742, and the fax number is (202) 566-9744. An electronic version of the public docket is available through the federal government's electronic public docket and comment system at <http://>

[www.regulations.gov](http://www.regulations.gov). After opening the [www.regulations.gov](http://www.regulations.gov) Web site, enter EPA-HQ-OAR-2016-0017 in the “Enter Keyword or ID” fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information (“CBI”) or other information whose disclosure is restricted by statute.

EPA’s Office of Transportation and Air Quality (“OTAQ”) maintains a Web page that contains general information on its review of California waiver and authorization requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today’s notice; the page can be accessed at <http://www.epa.gov/otaq/cafr.htm>.

**FOR FURTHER INFORMATION CONTACT:** David Dickinson, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Telephone: (202) 343-9256. Email: [dickinson.david@epa.gov](mailto:dickinson.david@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On August 19, 2005, EPA granted California a waiver of preemption pursuant to section 209(b) of the CAA, 42 U.S.C. 7543(b), for CARB’s amendments to its heavy-duty diesel engine standards for 2007 and subsequent model year (MY) vehicles and engines and related test procedures, including not-to-exceed (“NTE”) and supplemental steady-state tests to determine compliance with applicable standards (“2007 California HDDE standards”).<sup>1</sup> Those standards apply to all heavy-duty diesel engines, and align California’s standards and test procedures with corresponding federal standards and test procedures. In 2010 EPA granted California a waiver of preemption for CARB’s adoption of amendments applicable to 2008 and subsequent MY heavy-duty Otto-cycle engines.<sup>2</sup> In 2005, CARB adopted truck idling requirements, including an element whereby new California-certified 2008 and subsequent MY on-road diesel engines in trucks with a gross vehicle weight rating (“GVWR”) greater than 14,000 pounds were required to be equipped with a system that automatically shuts down the engine after five minutes of continuous idling (“Truck Idling regulation”). In lieu of the automatic engine shutdown systems, manufacturers are allowed to optionally certify engines to a NO<sub>x</sub>

idling emission standard. EPA granted a waiver for the Truck Idling regulation in 2012.<sup>3</sup>

CARB’s In-Use Regulation establishes a manufacturer-run in-use compliance program that is largely identical to EPA’s previously adopted heavy-duty in-use testing program (“HDIUT program”) originally adopted in 2005.<sup>4</sup> The regulation applies to 2007 and subsequent MY engine-dynamometer certified heavy-duty diesel engines installed in a motor vehicle with GVWR greater than 8,500 pounds. CARB’s initial In-Use Regulation, adopted in 2006, included requirements for manufacturers screening test vehicles with portable emission measurement systems (PEMS) and testing the vehicles by operating them over typical driving routes, and under the same vehicle loads and environmental conditions that the vehicles routinely encounter. The in-use compliance program is comprised of two phases. The first phase, Phase 1, involves testing a designated engine family for conformity with the applicable NTE requirements. In the second phase, if the engine family does not pass the Phase 1 requirements then testing, under more narrowly defined test conditions, may be required to target specific noncomplying operating conditions. The initial regulation incorporated temporary measurement allowances when testing for compliance using PEMS. In 2007, CARB amended the In-Use Regulation to set forth new measurement allowances for gaseous emissions.<sup>5</sup> In 2011, CARB approved additional amendments to the In-Use Requirements to establish a new particulate matter (“PM”) measurement allowance. EPA similarly amended its federal HDIUT program in 2010 to incorporate this same measurement allowance.<sup>6</sup>

CARB initially adopted the 2007 California HDDE standards in 2001 to fully align California’s NO<sub>x</sub> emission standards for 2007 and subsequent MY HDDEs and medium-duty diesel engines (“MDDEs”) certified to ultra-low-emission vehicle (“ULEV”) standards to the corresponding federal NO<sub>x</sub> emission standard of 0.20 gram per brake-horsepower hour (g/bhp-hr) (two significant figures). CARB also established a more stringent NO<sub>x</sub> standard for MDDEs certified to optional ultra-low-emission vehicle (“SULEV”)

emission standards of 0.10 g/bhp-hr). CARB’s 2007 Amendments clarify that the NO<sub>x</sub> ULEV emission standard for HDDEs is the same as the federal NO<sub>x</sub> emission standard of 0.20 g/bhp-hr and amended the NO<sub>x</sub> SULEV standard to 0.10 g/bhp-hr (CARB had inadvertently specified these NO<sub>x</sub> emission standards to only one significant figure (0.2 and 0.1 g/bhp-hr, respectively)). CARB had also inadvertently failed to include a provision that provided manufacturers the option to include chassis-certified 2007 through 2009 MY heavy-duty diesel vehicles under 14,000 pounds GVWR within the phase-in compliance provision of the 2007 HDDE standards. The 2007 Amendments incorporate this optional provision. In addition, the 2007 Amendments incorporate the flexibility provided by EPA in 2006, whereby manufacturers may apply multiplicative deterioration factors if, based on good engineering judgment, multiplicative deterioration factors are more appropriate for a particular engine family (as opposed to an adjustment by the addition of appropriate deterioration factors).<sup>7</sup>

In 2008 CARB adopted amendments to the new engine requirements within the Truck Idling regulation to address specific issues regarding armored cars and workover rigs. Specifically, the Truck Idling Amendments provide that new 2008 and subsequent MY heavy-duty diesel engines used in armored cars and workover rigs are exempt from the new engine idling requirements. In addition, in 2011 CARB provided additional regulatory clarification of the exemption.<sup>8</sup>

By letter dated January 27, 2016, CARB submitted to EPA a request for a waiver of the preemption found at section 209(a) of Clean Air Act, 42 U.S.C. 7543(a), for the In-Use Regulation. CARB’s submission provided analysis and evidence to support its finding that the In-Use Regulation satisfies the CAA section 209(b) criteria and that a waiver of preemption should be granted. CARB’s request also sought confirmation that its 2007 Amendments and the Truck Idling Amendments are within the scope of waivers of preemption previously granted by EPA.<sup>9</sup>

**II. Principles Governing This Review**

*A. Scope of Review*

Section 209(a) of the CAA provides:

No State or any political subdivision thereof shall adopt or attempt to enforce any

<sup>7</sup> *Id.* at 11, *citing* 71 FR 51481 (August 30, 2006).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>3</sup> 77 FR 9239 (February 16, 2012).

<sup>4</sup> 70 FR 34594 (June 14, 2005).

<sup>5</sup> See the California Air Resources Board’s Waiver Request Support Document (“Waiver Support Document”), dated December 31, 2015 at EPA-HQ-OAR-2016-0017-0018, at 7–8.

<sup>6</sup> Waiver Support Document at 9, *citing* 75 FR 68448 (November 8, 2010).

<sup>1</sup> 70 FR 50322 (August 26, 2005).

<sup>2</sup> 75 FR 70237 (November 17, 2010).

standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No State shall require certification, inspection or any other approval relating to the control of emissions from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.<sup>10</sup>

Section 209(b)(1) of the Act requires the Administrator, after an opportunity for public hearing, to waive application of the prohibitions of section 209(a) for any state that has adopted standards (other than crankcase emission standards) for the control of emissions from new motor vehicles or new motor vehicle engines prior to March 30, 1966, if the state determines that its state standards will be, in the aggregate, at least as protective of public health and welfare as applicable federal standards.<sup>11</sup> However, no such waiver shall be granted if the Administrator finds that: (A) The protectiveness determination of the state is arbitrary and capricious; (B) the state does not need such state standards to meet compelling and extraordinary conditions; or (C) such state standards and accompanying enforcement procedures are not consistent with section 202(a) of the Act.<sup>12</sup>

Key principles governing this review are that EPA should limit its inquiry to the specific findings identified in section 209(b)(1) of the Clean Air Act, and that EPA will give substantial deference to the policy judgments California has made in adopting its regulations. In previous waiver decisions, EPA has stated that Congress intended the Agency's review of California's decision-making to be narrow. EPA has rejected arguments that are not specified in the statute as grounds for denying a waiver:

The law makes it clear that the waiver requests cannot be denied unless the specific findings designated in the statute can properly be made. The issue of whether a proposed California requirement is likely to result in only marginal improvement in California air quality not commensurate with its costs or is otherwise an arguably unwise exercise of regulatory power is not legally pertinent to my decision under section 209, so long as the California requirement is consistent with section 202(a) and is more stringent than applicable Federal requirements in the sense that it may result

in some further reduction in air pollution in California.<sup>13</sup>

This principle of narrow EPA review has been upheld by the U.S. Court of Appeals for the District of Columbia Circuit.<sup>14</sup> “[T]he statute does not provide for any probing substantive review of the California standards by federal officials.” *Ford Motor Co. v. EPA*, 606 F.2d 1293, 1300 (D.C. Cir. 1979). Thus, EPA's consideration of all the evidence submitted concerning a waiver decision is circumscribed by its relevance to those questions that may be considered under section 209(b)(1).

#### B. Within-the-Scope Determinations

If California amends regulations that have been previously authorized by EPA, California may ask EPA to determine that the amendments are within the scope of the earlier authorization. A within-the-scope determination for such amendments is permissible without a full authorization review if three conditions are met. First, the amended regulations must not undermine California's previous determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 209 of the Act, following the same criteria discussed above in the context of full authorizations. Third, the amended regulations must not raise any new issues affecting EPA's prior waiver or authorization decisions.<sup>15</sup>

#### C. Burden and Standard of Proof

As the U.S. Court of Appeals for the D.C. Circuit has made clear in *MEMA I*, opponents of a waiver request by California bear the burden of showing that the statutory criteria for a denial of the request have been met:

[T]he language of the statute and its legislative history indicate that California's regulations, and California's determinations that they must comply with the statute, when presented to the Administrator are presumed to satisfy the waiver requirements and that the burden of proving otherwise is on whoever attacks them. California must present its regulations and findings at the hearing and thereafter the parties opposing

the waiver request bear the burden of persuading the Administrator that the waiver request should be denied.<sup>16</sup>

The Administrator's burden, on the other hand, is to make a reasonable evaluation of the information in the record in coming to the waiver decision. As the court in *MEMA I* stated: “here, too, if the Administrator ignores evidence demonstrating that the waiver should not be granted, or if he seeks to overcome that evidence with unsupported assumptions of his own, he runs the risk of having his waiver decision set aside as ‘arbitrary and capricious.’”<sup>17</sup> Therefore, the Administrator's burden is to act “reasonably.”<sup>18</sup>

With regard to the standard of proof, the court in *MEMA I* explained that the Administrator's role in a section 209 proceeding is to:

[. . .] consider all evidence that passes the threshold test of materiality and . . . thereafter assess such material evidence against a standard of proof to determine whether the parties favoring a denial of the waiver have shown that the factual circumstances exist in which Congress intended a denial of the waiver.<sup>19</sup>

In that decision, the court considered the standards of proof under section 209 for the two findings related to granting a waiver for an “accompanying enforcement procedure.” Those findings involve: (1) Whether the enforcement procedures impact California's prior protectiveness determination for the associated standards, and (2) whether the procedures are consistent with section 202(a). The principles set forth by the court are similarly applicable to an EPA review of a request for a waiver of preemption for a standard. The court instructed that “the standard of proof must take account of the nature of the risk of error involved in any given decision, and it therefore varies with the finding involved. We need not decide how this standard operates in every waiver decision.”<sup>20</sup>

With regard to the protectiveness finding, the court upheld the Administrator's position that, to deny a waiver, there must be “clear and compelling evidence” to show that proposed enforcement procedures undermine the protectiveness of California's standards.<sup>21</sup> The court noted that this standard of proof also accords with the congressional intent to provide California with the broadest

<sup>13</sup> “Waiver of Application of Clean Air Act to California State Standards,” 36 FR 17458 (Aug. 31, 1971). Note that the more stringent standard expressed here, in 1971, was superseded by the 1977 amendments to section 209, which established that California must determine that its standards are, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

<sup>14</sup> See, e.g., *Motor and Equip. Mfrs Assoc. v. EPA*, 627 F.2d 1095 (D.C. Cir. 1979) (“*MEMA I*”).

<sup>15</sup> See “California State Motor Vehicle Pollution Control Standards; Amendments Within the Scope of Previous Waiver of Federal Preemption,” 46 FR 36742 (July 15, 1981).

<sup>16</sup> *MEMA I*, note 19, at 1121.

<sup>17</sup> *Id.* at 1126.

<sup>18</sup> *Id.* at 1126.

<sup>19</sup> *Id.* at 1122.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>10</sup> CAA § 209(a). 42 U.S.C. 7543(a).

<sup>11</sup> CAA § 209(b)(1). 42 U.S.C. 7543(b)(1).

California is the only state that meets section 209(b)(1)'s requirement for obtaining a waiver. See S. Rep. No. 90–403 at 632 (1967).

<sup>12</sup> CAA § 209(b)(1). 42 U.S.C. 7543(b)(1).

possible discretion in setting regulations it finds protective of the public health and welfare.<sup>22</sup>

With respect to the consistency finding, the court did not articulate a standard of proof applicable to all proceedings, but found that the opponents of the waiver were unable to meet their burden of proof even if the standard were a mere preponderance of the evidence. Although *MEMA I* did not explicitly consider the standards of proof under section 209 concerning a waiver request for “standards,” as compared to a waiver request for accompanying enforcement procedures, there is nothing in the opinion to suggest that the court’s analysis would not apply with equal force to such determinations. EPA’s past waiver decisions have consistently made clear that: “[E]ven in the two areas concededly reserved for Federal judgment by this legislation—the existence of ‘compelling and extraordinary’ conditions and whether the standards are technologically feasible—Congress intended that the standards of EPA review of the State decision to be a narrow one.”<sup>23</sup>

#### D. Deference to California

In previous waiver decisions, EPA has recognized that the intent of Congress in creating a limited review based on specifically listed criteria was to ensure that the federal government did not second-guess state policy choices. As the Agency explained in one prior waiver decision:

It is worth noting . . . I would feel constrained to approve a California approach to the problem which I might also feel unable to adopt at the federal level in my own capacity as a regulator. . . . Since a balancing of risks and costs against the potential benefits from reduced emissions is a central policy decision for any regulatory agency under the statutory scheme outlined above, I believe I am required to give very substantial deference to California’s judgments on this score.<sup>24</sup>

Similarly, EPA has stated that the text, structure, and history of the California waiver provision clearly indicate both a congressional intent and appropriate EPA practice of leaving the decision on “ambiguous and controversial matters of public policy” to California’s judgment.<sup>25</sup> This interpretation is supported by relevant discussion in the House Committee

Report for the 1977 amendments to the CAA. Congress had the opportunity through the 1977 amendments to restrict the preexisting waiver provision, but elected instead to expand California’s flexibility to adopt a complete program of motor vehicle emission controls. The report explains that the amendment is intended to ratify and strengthen the preexisting California waiver provision and to affirm the underlying intent of that provision, that is, to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare.<sup>26</sup>

#### E. EPA’s Administrative Process in Consideration of California’s Request

On August 9, 2016, EPA published a notice of opportunity for public hearing and comment on California’s waiver request.<sup>27</sup> In that notice, EPA requested comments on whether the 2007 Amendments and the Truck Idling Amendments, each individually assessed, should be considered under the within-the-scope analysis or whether they should be considered under the full waiver criteria. For the In-Use Regulation, and to the degree the 2007 Amendments or the Truck Idling Amendments should not be considered under the within-the-scope criteria, EPA sought comment under the following three criteria: Whether (a) California’s determination that its motor vehicle emissions standards are, in the aggregate, at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) California needs such State standards to meet compelling and extraordinary conditions, and (c) California’s standards and accompanying enforcement procedures are consistent with section 202(a) of the Clean Air Act.

EPA received no comments and no requests for a public hearing. Consequently, EPA did not hold a public hearing.

### III. Discussion

#### A. Within-the-Scope Analysis

EPA initially evaluates California’s 2007 Amendments and Truck Idling Amendments by application of our traditional within-the-scope analysis, as CARB requested. If we determine that CARB’s request does not meet the requirements for a within-the-scope determination, we then evaluate the request based on a full authorization analysis. In determining whether amendments can be viewed as within

the scope of previous waivers, EPA looks at whether CARB’s revision is either limited to minor technical amendments to previously waived regulations or modifying regulations in order to provide additional compliance flexibility without significantly reducing the overall stringency of previously waived regulations. The amendments at issue in this request provide regulatory clarity and corrections, and provide limited exemptions in order to provide for compliance flexibility.

EPA sought comment on a range of issues, including those applicable to a within-the-scope analysis as well as those applicable to a full authorization analysis. No party submitted a comment that California’s 2007 Amendments or Truck Idling Amendments require a full authorization analysis. Given the lack of comments on this issue, and EPA’s assessment of the nature of the amendments, I will evaluate California’s 2007 amendments and Truck Idling Amendments by application of the traditional within-the-scope analysis, as CARB requested.

As noted above, EPA can confirm that the amended regulations are within the scope of a previously granted waiver of preemption if three conditions are met. First, the amended regulations do not undermine California’s determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations do not affect consistency with section 202(a) of the Act. Third, the amended regulations do not raise any “new issues” affecting EPA’s prior authorizations.

#### B. Full Authorization Analysis

CARB’s waiver request also included the In-Use Regulation. EPA must grant a waiver for the In-Use Regulation unless the Administrator finds: (1) California’s determination that its standards will be, in the aggregate, as protective of public health and welfare as applicable federal standards is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California’s standards and accompanying enforcement procedures are not consistent with this section.

EPA’s evaluation of the 2007 Amendments, the Truck Idling Amendments, and the In-use Regulation is set forth below. Because of the similarity of the within-the-scope criteria and the full waiver criteria, a discussion of all three sets of respective amendments take place within each waiver criterion. To the extent that the

<sup>22</sup> *Id.*

<sup>23</sup> See, e.g., “California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption,” 40 FR 23102 (May 28, 1975), at 23103.

<sup>24</sup> 40 FR 23102, 23103–04 (May 28, 1975).

<sup>25</sup> 40 FR 23102, 23104 (May 28, 1975); 58 FR 4166 (January 13, 1993).

<sup>26</sup> *MEMA I*, 627 F.2d at 1110 (citing H.R. Rep. No. 294, 95th Cong., 1st Sess. 301–02 (1977)).

<sup>27</sup> 81 FR 52678 (August 9, 2016).

criteria are applied uniquely, or that additional criteria apply under either the within-the-scope analysis or the full waiver analysis, such application is also addressed below.

*C. Whether California's Protectiveness Determination Was Arbitrary and Capricious*

As stated in the background, section 209(b)(1)(A) of the Act sets forth the first of the three criteria governing a new waiver request—whether California was arbitrary and capricious in its determination that its motor vehicle emissions standards will be, in the aggregate, at least as protective of public health and welfare as applicable federal standards. Section 209(b)(1)(A) of the CAA requires EPA to deny a waiver if the Administrator finds that California's protectiveness determination was arbitrary and capricious. However, a finding that California's determination was arbitrary and capricious must be based upon clear and convincing evidence that California's finding was unreasonable.<sup>28</sup>

CARB notes that in its initial adoption and amendments to the In-Use Regulation in 2006, 2007, and 2011, the CARB Board approved Resolutions 06–27, 07–56 and 11–19 in which it declared:

*Be it further resolved* that the Board hereby determines that the regulations adopted herein will not cause California motor vehicle emission standards, in the aggregate, to be less protective of the public health and welfare than applicable federal standards.<sup>29</sup>

CARB also notes that EPA has previously granted California a waiver for California's 2007 California HDDE standards (which included the NTE test procedures), and the addition of the In-Use Regulation will help ensure that the emission control systems on HDDEs are properly designed and sufficiently durable to ensure compliance with the emission requirements during their useful life. CARB further noted that the In-Use Regulation provisions are “essentially identical to the requirements of EPA's corresponding HDIUT program.”<sup>30</sup> CARB also notes that the 2007 Amendments in no way undermine the stringency of the underlying exhaust emission standards or the associated test procedures (which is the criterion under the within-the-

scope analysis), but instead ensure that California's standards remain as, or more protective than, applicable federal standards.<sup>31</sup> Similarly, CARB notes that with regard to the Truck Idling Amendments that EPA's regulations do not require new heavy-duty diesel engines to be equipped with idling shutdown systems or to optionally comply with NO<sub>x</sub> idling emission standards.<sup>32</sup>

As it is clear that California's standards are at least as protective of public health and welfare as applicable federal standards, and that no evidence is in the record suggesting otherwise (and EPA is not otherwise aware of any information), I find that California's respective protectiveness determinations are not arbitrary and capricious for purposes of the In-Use Regulation, the 2007 Amendments, and the Truck Idling Amendments.

*D. Whether the Standards Are Necessary To Meet Compelling and Extraordinary Conditions*

Section 209(b)(1)(B) instructs that EPA cannot grant a waiver if the Agency finds that California “does not need such State standards to meet compelling and extraordinary conditions.” EPA's inquiry under this second criterion has traditionally been to determine whether California needs its own motor vehicle emission control program (*i.e.*, set of standards) to meet compelling and extraordinary conditions, and not whether the specific standards that are the subject of the waiver request are necessary to meet such conditions.<sup>33</sup> In recent waiver actions, EPA again examined the language of section 209(b)(1)(B) and reiterated this longstanding traditional interpretation as the better approach for analyzing the need for “such State standards” to meet “compelling and extraordinary conditions.”<sup>34</sup>

<sup>31</sup> *Id.* at 21.

<sup>32</sup> *Id.* at 24, citing Resolution 11–19.

<sup>33</sup> See California State Motor Vehicle Pollution Control Standards; Notice of Decision Granting a Waiver of Clean Air Act Preemption for California's 2009 and Subsequent Model Year Greenhouse Gas Emission Standards for New Motor Vehicles,” 74 FR 32744 (July 8, 2009), at 32761; see also “California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption Notice of Decision,” 49 FR 18887 (May 3, 1984), at 18889–18890.

<sup>34</sup> See 78 FR 2112, at 2125–26 (Jan. 9, 2013) (“EPA does not look at whether the specific standards at issue are needed to meet compelling and extraordinary conditions related to that air pollutant.”; see also EPA's July 9, 2009 GHG Waiver Decision wherein EPA rejected the suggested interpretation of section 209(b)(1)(B) as requiring a review of the specific need for California's new motor vehicle greenhouse gas emission standards as opposed to the traditional interpretation (need for the motor vehicle emission program as a whole) applied to local or regional air pollution problems. See also 79 FR 46256, 46261 (August 7, 2014).

In conjunction with the initial adoption and subsequent amendments of the In-Use Regulation in 2006, 2007, and 2011, respectively (see Resolutions 06–27, 07–56, and 11–19 noted above), the CARB's Board confirmed California's longstanding position that California continues to need its own motor vehicle emission program to meet serious air pollution problems. CARB notes that the geographical and climatic conditions and the tremendous growth in vehicle population and use that moved Congress to authorize California to establish separate vehicle standards in 1967 still exist today.<sup>35</sup> “Nothing in these conditions has changed to warrant a change in EPA's confirmation, and therefore there can be no doubt of the continuing existence of compelling and extraordinary conditions justifying California's need for its own motor vehicle emissions control program.”<sup>36</sup>

There has been no evidence submitted to indicate that California's compelling and extraordinary conditions do not continue to exist. California, particularly in the South Coast and San Joaquin Valley air basins, continues to experience some of the worst air quality in the nation, and many areas in California continue to be in non-attainment with national ambient air quality standards for fine particulate matter and ozone.<sup>37</sup> As California has previously stated, “nothing in [California's unique geographic and climatic] conditions has changed to warrant a change in this determination.”<sup>38</sup>

Based on the record before us, including EPA's prior waiver decisions, I am unable to identify any change in circumstances or evidence to suggest that the conditions that Congress identified as giving rise to serious air quality problems in California no longer exist. Therefore, EPA cannot find that California does not need its state standards, including its In-Use

<sup>35</sup> Waiver Support Request Support Document at 18.

<sup>36</sup> *Id.*

<sup>37</sup> 74 FR 32744, 32762–63 (July 8, 2009), 76 FR 77515, 77518 (December 13, 2011), 81 FR 95982 (December 29, 2016). EPA continually evaluates the air quality conditions in the United States, including California. California continues to experience some of the worst air quality in the country and continues to be in nonattainment with National Ambient Air Quality Standards for fine particulate matter and ozone, see “Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS)” at EPA–HQ–OAR–2016–0751.

<sup>38</sup> *Id.*

<sup>28</sup> *MEMA I*, 627 F.2d at 1122, 1124 (“Once California has come forward with a finding that the procedures it seeks to adopt will not undermine the protectiveness of its standards, parties opposing the waiver request must show that this finding is unreasonable.”); see also 78 FR 2112, at 2121 (January 9, 2013).

<sup>29</sup> Waiver Support Document at 17. See EPA–HQ–OAR–2016–0017–0027, EPA–HQ–OAR–2016–0017–0047, and EPA–HQ–OAR–2016–0017–0056.

<sup>30</sup> *Id.*

Regulation, to meet compelling and extraordinary conditions in California.

#### *E. Consistency With Section 202(a)*

For the third and final criterion, EPA evaluates the program for consistency with section 202(a) of the CAA. Under section 209(b)(1)(C) of the CAA, EPA must deny California's waiver request if EPA finds that California's standards and accompanying enforcement procedures are not consistent with section 202(a). Section 202(a) requires that regulations "shall take effect after such period as the Administrator finds necessary to permit the development and application of the relevant technology, considering the cost of compliance within that time."

EPA has previously stated that the determination is limited to whether those opposed to the waiver have met their burden of establishing that California's standards are technologically infeasible, or that California's test procedures impose requirements inconsistent with the federal test procedure. Infeasibility would be shown here by demonstrating that there is inadequate lead time to permit the development of technology necessary to meet the In-Use Amendments, the 2007 Amendments, or the Truck Idling Amendments that are the subject of the waiver request, giving appropriate consideration to the cost of compliance within that time.<sup>39</sup> California's accompanying enforcement procedures would also be inconsistent with section 202(a) if the federal and California test procedures conflicted, *i.e.*, if manufacturers would be unable to meet both the California and federal test requirements with the same test vehicle.<sup>40</sup>

Regarding test procedure conflict, CARB notes both EPA and CARB utilize essentially identical test procedures in certifying 2007 and subsequent MY heavy-duty engines and that the 2007 Amendments also do not preclude manufacturers from conducting one set of tests on a heavy-duty engine or vehicle to determine compliance with both the California and federal requirements.<sup>41</sup> For the reasons set forth above, and because there is no evidence in the record or other information that EPA is aware of, I cannot find that CARB's In-Use Compliance Regulation, 2007 Amendments, and Truck Idling Amendments are inconsistent with

section 202(a) based upon test procedure inconsistency.

In addition, EPA did not receive any comments arguing that the CARB's In-Use Regulation, 2007 Amendments, and Truck Idling Amendments were technologically infeasible or that the cost of compliance would be excessive, such that California's standards might be inconsistent with section 202(a).<sup>42</sup> In EPA's review of CARB's In-Use Regulation, I find that CARB's statements about the capability of PEMS technology to measure gaseous pollutants as well as PM emissions is accurate.<sup>43</sup> With regard to the 2007 Amendments, I find that the amendments do not raise any new issues regarding technological feasibility given that the amendments regarding how the NO<sub>x</sub> standard is expressed is a regulatory clarification and the amendment regarding the new option for certain chassis-certified 2007 through 2009 model year heavy-duty vehicles provides additional compliance flexibility. Similarly, the Truck Idling Amendments merely provide compliance flexibility to a previously waived program by setting forth limited compliance exemptions (*i.e.*, the exemptions for armored vehicles and workover rigs).

I therefore cannot find that California standards, which include the CARB's In-Use Regulation, 2007 Amendments, and Truck Idling Amendments are inconsistent with section 202(a).

#### *F. New Issues*

EPA has stated in the past that if California promulgates amendments that raise new issues affecting previously granted waivers, we would not confirm that those amendments are within the scope of previous waivers.<sup>44</sup> I do not believe that either the 2007 Amendments or the Truck Idling Amendments raise any new issues with respect to our prior waivers governing their underlying regulations. Moreover, EPA did not receive any comments that CARB's 2007 Amendments or Truck Idling Amendments raised new issues affecting the previously granted waivers. Therefore, I cannot find that CARB's 2007 Amendments and Truck Idling

Amendments raise new issues and consequently, cannot deny CARB's within-the-scope requests based on this criterion.

#### **IV. Decision**

After evaluating CARB's In-Use Regulation and CARB's submissions for EPA review, I am hereby granting a waiver for the In-Use Regulation. After evaluating CARB's 2007 Amendments and Truck Idling Amendments and CARB's submissions for EPA review, I am hereby confirming that such amendments are within the scope of prior EPA waivers.

This decision will affect persons in California and those manufacturers and/or owners/operators nationwide who must comply with California's requirements. In addition, because other states may adopt California's standards for which a section 209(b) waiver has been granted under section 177 of the Act if certain criteria are met, this decision would also affect those states and those persons in such states. For these reasons, EPA determines and finds that this is a final action of national applicability, and also a final action of nationwide scope or effect for purposes of section 307(b)(1) of the Act. Pursuant to section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 20, 2017. Judicial review of this final action may not be obtained in subsequent enforcement proceedings, pursuant to section 307(b)(2) of the Act.

#### **V. Statutory and Executive Order Reviews**

As with past waiver and authorization decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

<sup>39</sup> See, *e.g.*, 38 FR 30136 (November 1, 1973) and 40 FR 30311 (July 18, 1975).

<sup>40</sup> See, *e.g.*, 43 FR 32182 (July 25, 1978).

<sup>41</sup> *Id.* at 20, 22.

<sup>42</sup> See, *e.g.*, 78 FR 2134 (January 9, 2013), 47 FR 7306, 7309 (February 18, 1982), 43 FR 25735 (June 17, 1978), and 46 FR 26371, 26373 (May 12, 1981).

<sup>43</sup> Waiver Support Document at 19 (CARB explains that several PEMS capable of measuring gaseous emissions are commercially available and that the further development needed (at the time of CARB's initial adoption of the In-Use Regulation) for PM emissions monitoring by PEMS has been resolved.

<sup>44</sup> See, *e.g.*, 78 FR 38970 (June 28, 2013), 75 FR 8056 (February 23, 2010), and 70 FR 22034 (April 28, 2005).



Dated: January 9, 2017.

**Gina McCarthy,**  
Administrator.

[FR Doc. 2017-00940 Filed 1-13-17; 8:45 am]

BILLING CODE 6560-50-P

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## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0989]

### Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written PRA comments should be submitted on or before March 20, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicole Ongele, FCC, via email to [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Nicole.Ongele@fcc.gov](mailto:Nicole.Ongele@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Nicole Ongele at (202) 418-2991.

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 3060-0989.

*Title:* Sections 63.01, 63.03, 63.04, Procedures for Applicants Requiring Section 214 Authorization for Domestic Interstate Transmission Lines Acquired Through Corporate Control.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents of Responses:* 92 respondents; 92 responses.

*Estimated Time per Response:* 1.5-10 hours.

*Frequency of Response:* On occasion reporting requirement.

*Obligation to Respond:* Mandatory. Statutory authority for this collection is contained in 47 U.S.C. 152, 154(i)-(j), 201, 214, and 303(r).

*Total Annual Burden:* 861 hours.

*Annual Cost Burden:* \$98,175.

*Privacy Act Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* There is no need for confidentiality. The FCC is not requiring applicants to submit confidential information to the Commission. If applicants want to request confidential treatment of the documents they submit to Commission, they may do so under 47 CFR 0.459 of the Commission's rules.

*Needs and Uses:* A Report and Order, FCC 02-78, adopted and released in March 2002 (Order), set forth the procedures for common carriers requiring authorization under section 214 of the Communications Act of 1934, as amended, to acquire domestic interstate transmission lines through a transfer of control. Under section 214 of the Act, carriers must obtain FCC approval before constructing, acquiring, or operating an interstate transmission line. Acquisitions involving interstate common carriers require affirmative action by the Commission before the acquisition can occur. This information collection contains filing procedures for domestic transfer of control applications under sections 63.03 and 63.04. The FCC filing fee amount for section 214 applications is currently \$1,155 per application, which reflects an increase of the previous fee of \$1,050 per application. (a) Sections 63.03 and 63.04 require domestic section 214 applications involving domestic transfers of control, at a minimum, should specify: (1) The name, address and telephone number of each

applicant; (2) the government, state, or territory under the laws of which each corporate or partnership applicant is organized; (3) the name, title, post office address, and telephone number of the officer or contact point, such as legal counsel, to whom correspondence concerning the application is to be addressed; (4) the name, address, citizenship and principal business of any person or entity that directly or indirectly owns at least ten percent of the equity of the applicant, and the percentage of equity owned by each of those entities (to the nearest one percent); (5) certification pursuant to 47 CFR 1.2001 that no party to the application is subject to a denial of Federal benefits pursuant to section 5301 of the Anti-Drug Abuse Act of 1988; (6) a description of the transaction; (7) a description of the geographic areas in which the transferor and transferee (and their affiliates) offer domestic telecommunications services, and what services are provided in each area; (8) a statement as to how the application fits into one or more of the presumptive streamlined categories in section 63.03 or why it is otherwise appropriate for streamlined treatment; (9) identification of all other Commission applications related to the same transaction; (10) a statement of whether the applicants are requesting special consideration because either party to the transaction is facing imminent business failure; (11) identification of any separately filed waiver request being sought in conjunction with the transaction; and (12) a statement showing how grant of the application will serve the public interest, convenience, and necessity, including any additional information that may be necessary to show the effect of the proposed transaction on competition in domestic markets. Where an applicant wishes to file a joint international section 214 transfer of control application and domestic section 214 transfer of control application, the applicant must submit information that satisfies the requirements of 47 CFR 63.18. In the attachment to the international application, the applicant must submit information described in 47 CFR 63.04(a)(6). When the Commission, acting through the Wireline Competition Bureau, determines that applicants have submitted a complete application qualifying for streamlined treatment, it shall issue a public notice commencing a 30-day review period to consider whether the transaction serves the public interest, convenience and necessity. Parties will have 14 days to



file any comments on the proposed transaction, and applicants will be given 7 days to respond. (b) Applicants are not required to file post-consummation notices of pro forma transactions, except that a post transaction notice must be filed with the Commission within 30 days of a pro forma transfer to a bankruptcy trustee or a debtor-in-possession. The notification can be in the form of a letter (in duplicate to the Secretary, Federal Communications Commission). The letter or other form of notification must also contain the information listed in sections (a)(1). A single letter may be filed for more than one such transfer of control. The information will be used by the Commission to ensure that applicants comply with the requirements of 47 U.S.C. 214.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-00849 Filed 1-13-17; 8:45 am]

BILLING CODE 6712-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0881]

### Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information

collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written PRA comments should be submitted on or before March 20, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060-0881.

*Title:* Section 95.861, Interference.

*Form No.:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and Responses:* 175 respondents; 175 responses.

*Estimated Time per Response:* 1 hour.

*Frequency of Response:*

Recordkeeping requirement, third party disclosure requirement, and on occasion reporting requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 154(i) and 157, as amended.

*Total Annual Burden:* 175 hours.

*Annual Cost Burden:* \$43,700.

*Privacy Act Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Needs and Uses:* The information collection requirements contained in 47 Section 95.861(c) require that licensees in the 218-219 MHz service must provide a copy of its plan to every TV Channel 13 station whose Grade B predicted contour overlaps the licensed service area as required by § 95.815(a) of the Commission's rules. This plan must include an analysis of the co- and adjacent channel interference potential of proposed systems in the 218-219 MHz service, identify methods being used to minimize interference, and show how the proposed systems will

meet the service requirements set forth in § 95.831 of the Commission's rules. This plan must be sent to the TV Channel 13 licensee(s) within 10 days from the date the 218-219 MHz service licensee submits the plan to the Commission. Updates to this plan must be sent to the TV Channel 13 licensee(s) within 10 days from the date that such updates are filed with the Commission pursuant to § 95.815.

The information collection requirements contained in 47 Section 95.861(e) require that each 218-219 MHz service licensee investigate and eliminate harmful interference to television broadcasting and reception, from its component cell transmitter stations (CTSs) and response transmitter units (RTUs) within 30 days of the time it is notified in writing, by either an affected television station, an affected viewer, or the Commission, of an interference complaint.

This information will be used to monitor the co- and adjacent channel interference potential of proposed systems in the 218-219 MHz service, and to identify methods being used to minimize interference, as well as to show how the proposed systems will meet the service requirements set forth in § 95.831 of the Commission's rules.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-00883 Filed 1-13-17; 8:45 am]

BILLING CODE 6712-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[3060-1126]

### Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility;

the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before February 16, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas\\_A\\_Fraser@omb.eop.gov](mailto:Nicholas_A_Fraser@omb.eop.gov); and to Nicole Ongele, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Nicole.Ongele@fcc.gov](mailto:Nicole.Ongele@fcc.gov). Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Nicole Ongele at (202) 418-2991.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <<http://www.reginfo.gov/public/do/PRAMain>>, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 3060-1126.

*Title:* Testing and Logging Requirements for Wireless Emergency Alerts (WEA).

*Form Number:* Not applicable.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and Responses:* 80 Participating CMS Providers; 451,600 Responses.

*Estimated Time per Response:* 0.000694 hours (2.5 seconds) to generate each alert log; 2 hours to respond to each request for alert log data or information about geo-targeting

*Frequency of Response:* Monthly and on occasion reporting requirements and recordkeeping requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154(i) and (o), 301, 301(r), 303(v), 307, 309, 335, 403, 544(g), 606 and 615 of the Communications Act of 1934, as amended, as well as by sections 602(a), (b), (c), (f), 603, 604 and 606 of the WARN Act.

*Total Annual Burden:* 125,390 hours.

*Total Annual Cost:* No cost.

*Privacy Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* Participating CMS Providers shall make available upon request to the Commission and FEMA, and to emergency management agencies that offer confidentiality protection at least equal to that provided in the federal Freedom of Information Act (FOIA) their alert logs and information about their approach to geo-targeting insofar as the information pertains to alerts initiated by that emergency management agency.

*Needs and Uses:* The Commission adopted revisions to Wireless Emergency Alert (WEA) rules to take advantage of the significant technological changes and improvements experienced by the mobile wireless industry since the passage of the Warning, Alert and Response Network (WARN) Act, and deployment of Wireless Emergency Alerts (WEA) to improve utility of WEA as a life-saving tool. This action will improve alert content, delivery and testing. With respect to information collection, in particular, the Commission adopted requirements for Participating CMS Providers to log the basic attributes of alerts they receive at their Alert Gateway, to maintain those logs for at least 12 months, and to make those logs available upon request to the Commission and FEMA, and to emergency management agencies that offer confidentiality protection at least equal to that provided by federal FOIA. The Commission also required Participating CMS Providers to disclose

information regarding their capabilities for geo-targeting Alert Messages upon request to such emergency management agencies insofar as it would pertain to Alert Messages initiated by that emergency management agency.

These recordkeeping and reporting requirements have potential to increase emergency managers' confidence that WEA will work as intended when needed. This increased confidence in system availability will encourage emergency managers that do not currently use WEA to become authorized. These reporting and recordkeeping requirements also help to ensure a fundamental component of system integrity. Alert logs are necessary to establish a baseline for system integrity against which future iterations of WEA can be evaluated. Without records that can be used to describe the quality of system integrity, and the most common causes of message transmission failure, it will be difficult to evaluate how any changes to WEA that we may adopt subsequent to this *Report and Order* affect system integrity.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-00850 Filed 1-13-17; 8:45 am]

**BILLING CODE 6712-01-P**

**FEDERAL COMMUNICATIONS COMMISSION**

[OMB 3060-0262 and 3060-0519]

**Information Collections Being Submitted for Review and Approval to the Office of Management and Budget**

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize

the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before February 16, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas\\_A.Fraser@omb.eop.gov](mailto:Nicholas_A.Fraser@omb.eop.gov); and to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov). Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Cathy Williams at (202) 418-2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060-0262.

*Title:* Section 90.179, Shared Use of Radio Stations.

*Form No.:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit, non-for-profit institutions, and state, local and tribal government.

*Number of Respondents and Responses:* 43,000 respondents, 43,000 responses.

*Estimated Time per Response:* .25 up to .75 hours.

*Frequency of Response:* Recordkeeping requirement and On occasion reporting requirement.

*Obligation To Respond:* Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7).

*Total Annual Burden:* 43,000 hours.

*Annual Cost Burden:* None.

*Privacy Act Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Needs and Uses:* The Commission was directed by the United States Congress, in the Balanced Budget Act of 1997, to dedicate 2.4 MHz of electromagnetic spectrum in the 746-806 MHz band for public safety services. Section 90.179 requires that Part 90 licensees that share use of their private land mobile radio facility on non-profit, cost-sharing basis to prepare and keep a written sharing agreement as part of the station records. Regardless of the method of sharing, an up-to-date list of persons who are sharing the station and the basis of their eligibility under Part 90 must be maintained. The requirement is necessary to identify users of the system should interference problems develop. This information is used by the Commission to investigate interference complaints and resolve interference and operational complaints that may arise among the users.

*OMB Control Number:* 3060-0519.

*Title:* Rules and Regulations Implementing the Telephone Consumer Protection Act (TCPA) of 1991, CG Docket No. 02-278.

*Form Number:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit entities; Individuals or households; Not-for-profit institutions.

*Number of Respondents and Responses:* 36,548 respondents; 147,434,797 responses.

*Estimated Time per Response:* .004 hours (15 seconds) to 1 hour.

*Frequency of Response:* Recordkeeping requirement; Annual, on occasion and one-time reporting requirement; Third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for the Information collection requirements is found in the Telephone

Consumer Protection Act of 1991 (TCPA), Public Law 102-243, December 20, 1991, 105 Stat. 2394, which added Section 227 of the Communications Act of 1934, [47 U.S.C. 227] Restrictions on the Use of Telephone Equipment.

*Total Annual Burden:* 666,598 hours.

*Total Annual Cost:* \$2,745,000.

*Nature and Extent of Confidentiality:* Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB-1, "Informal Complaints and Inquiries." As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB-1 "Informal Complaints, Inquiries, and Requests for Dispute Assistance", in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014. A system of records for the do-not-call registry was created by the Federal Trade Commission (FTC) under the Privacy Act. The FTC originally published a notice in the **Federal Register** describing the system. See 68 FR 37494, June 24, 2003. The FTC updated its system of records for the do-not-call registry in 2009. See 74 FR 17863, April 17, 2009.

*Privacy Impact Assessment:* Yes.

*Needs and Uses:* The reporting requirements included under this OMB Control Number 3060-0519 enable the Commission to gather information regarding violations of Section 227 of the Communications Act, the Do-Not-Call Implementation Act (Do-Not-Call Act), and the Commission's implementing rules. If the information collection were not conducted, the Commission would be unable to track and enforce violations of Section 227 of the Communications Act, the Do-Not-Call Act, or the Commission's implementing rules. The Commission's implementing rules provide consumers with protections from many unwanted telephone solicitations and other commercial calls.

The National Do-Not-Call Registry supplements the company-specific do-not-call rules for those consumers who wish to continue requesting that particular companies not call them. Any company that is asked by a consumer, including an existing customer, not to call again must honor that request for five (5) years.

A provision of the Commission's rules, however, allows consumers to give specific companies permission to call them through an express written agreement. Nonprofit organizations are exempt from the Do-Not-Call Registry requirements.

On September 21, 2004, the Commission released the *Safe Harbor Order* establishing a limited safe harbor in which callers will not be liable for placing autodialed and prerecorded message calls to numbers ported from a wireline service to a wireless service within the previous 15 days. The Commission also amended its existing National Do-Not-Call Registry safe harbor to require telemarketers to scrub their lists against the Registry every 31 days.

On June 17, 2008, in accordance with the Do-Not-Call Improvement Act of 2007, the Commission revised its rules to minimize the inconvenience to consumers of having to re-register their preferences not to receive telemarketing calls and to further the underlying goal of the National Do-Not-Call Registry to protect consumer privacy rights. The Commission released a *Report and Order* in CG Docket No. 02-278, FCC 08-147, amending the Commission's rules under the TCPA to require sellers and/or telemarketers to honor registrations with the National Do-Not-Call Registry so that registrations would not automatically expire based on the then-current five year registration period. Specifically, the Commission modified § 64.1200(c)(2) of its rules to require sellers and/or telemarketers to honor numbers registered on the Registry indefinitely or until the number is removed by the database administrator or the registration is cancelled by the consumer.

On February 15, 2012, the Commission released a *Report and Order* in CG Docket No. 02-278, FCC 12-21, revising its rules to: (1) Require prior express written consent for all autodialed or prerecorded telemarketing calls to wireless numbers and for all prerecorded telemarketing calls to residential lines; (2) eliminate the established business relationship exception to the consent requirement for prerecorded telemarketing calls to residential lines; (3) require telemarketers to include an automated, interactive opt-out mechanism in all prerecorded telemarketing calls, to allow consumers more easily to opt out of future robocalls during a robocall itself; and (4) require telemarketers to comply with the 3% limit on abandoned calls during each calling campaign, in order to discourage intrusive calling campaigns. Finally, the Commission also exempted from the Telephone Consumer Protection Act requirements prerecorded calls to residential lines made by health care-related entities governed by the Health Insurance Portability and Accountability Act of 1996.

On August 11, 2016, the Commission released a *Report and Order* in CG Docket No. 02-278, FCC 16-99, adopting rules to implement the TCPA amendments Congress enacted in Section 301 of the Bipartisan Budget Act of 2015. The Commission adopted rules implementing the law's exception from the prior express consent requirement for autodialed or prerecorded calls to wireless numbers "solely to collect a debt owed to or guaranteed by the United States," and placing limits on the number and duration of autodialed or prerecorded calls to wireless numbers "to collect a debt owed or guaranteed by the United States." Federal government callers and contractors making these calls on behalf of the federal government, without prior express consent of the called party, may call the person or persons responsible for paying the debt at one of three phone numbers specified in the rules, may call three times during a 30-day period, may call between 8:00 a.m. and 9:00 p.m. local time at the debtor's location, may not call once the debtor requests that the calls cease, and must transfer the stop-call request to the new servicer if the debt servicer changes. Callers must notify debtors of their right to request that no further autodialed or prerecorded calls be made to the debtor for the life of the debt. Prerecorded calls may not exceed 60 seconds, excluding required disclosures and stop-calling instructions. Text messages are limited to 160 characters, including required disclosures, which may be sent in a separate text message. Calls may be made (1) once the debt is delinquent and, (2) if the debt is not yet delinquent, then after one of the following events and in the 30 days before one of the following events: The end of a grace, deferment, or forbearance period; expiration of an alternative payment arrangement; or occurrence of a similar time-sensitive event or deadline affecting the amount or timing of payments due.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-00847 Filed 1-13-17; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1203 and 3060-0874]

### Information Collections Being Reviewed by the Federal Communications Commission

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before March 20, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060-1203.

*Title:* Section 79.107 User Interfaces Provided by Digital Apparatus; Section

79.108 Video Programming Guides and Menus Provided by Navigation Devices; Section 79.110 Complaint Procedures for User Interfaces, Menus and Guides, and Activating Accessibility Features on Digital Apparatus and Navigation Devices.

*Form No.:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Individuals or households; Business or other for-profit entities; Not for profit institutions; State, Local or Tribal government.

*Number of Respondents and Responses:* 4,175 respondents and 516,982 responses.

*Estimated Time per Response:* 0.0167 hours to 10 hours.

*Frequency of Response:* On occasion reporting requirement; Third party disclosure requirement; Recordkeeping requirement.

*Obligation to Respond:* Voluntary. The statutory authority for this information collection is contained in the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA), Public Law 111-260, 124 Stat. 2751, and sections 4(i), 4(j), 303(r), 303(u), 303(aa), 303(bb), and 716(g) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 303(r), 303(u), 303(aa), 303(bb), and 617(g).

*Total Annual Burden:* 24,043 hours.

*Annual Cost Burden:* \$70,500.

*Nature and Extent of Confidentiality:* Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB-1, "Informal Complaints, Inquiries, and Requests for Dispute Assistance." As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB-1 "Informal Complaints, Inquiries, and Requests for Dispute Assistance," in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014.

*Privacy Act Impact Assessment:* The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at <http://www.fcc.gov/omd/privacyact/Privacy-Impact-Assessment.html>. The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the SORN.

*Needs and Uses:*

On October 29, 2013, in document FCC 13-138, *Report and Order and Further Notice of Proposed Rulemaking (the User Interfaces Accessibility Order)*, MB Docket Nos. 12-108, 12-107,

published at 78 FR 77210, December 20, 2013, the Commission adopted rules implementing sections 204 and 205 of the CVAA related to making accessible the user interfaces, text menus and guides of digital apparatus designed to receive or play back video programming and navigation devices for the display or selection of multichannel video programming. On November 20, 2015, in document FCC 15-156, the Commission released a *Second Report and Order, Order on Reconsideration, and Second Further Notice of Proposed Rulemaking (the Second User Interfaces Accessibility Order)*, MB Docket No. 12-108, published at 81 FR 5921, February 14, 2016, adopting additional rules to ensure that consumers are able to find out about what accessible devices and features are available from covered manufacturers and multichannel video programming distributors (MVPDs) and how to use such devices and features. Collectively, these rules are codified at 47 CFR 79.107-79.110.

Covered entities are required to comply with the rules and information collection requirements contained in the *User Interfaces Accessibility Order* and in the *Second User Interfaces Accessibility Order* beginning December 20, 2016.

The Commission is submitting this revised information collection to transfer certain information collection burdens associated with this OMB Control Number 3060-1203 to OMB Control Number 3060-0874. This transfer is being made because the Commission's online consumer complaint portal, which is part of the information collection contained in OMB Control Number 3060-0874, is being revised to enable consumers to file complaints related to the Commission's user interfaces accessibility requirements through the Commission's online complaint portal.

*OMB Control Number:* 3060-0874.

*Title:* Consumer Complaint Portal: General Complaints, Obscenity or Indecency Complaints, Complaints under the Telephone Consumer Protection Act, Slamming Complaints, RDAs and Communications Accessibility Complaints.

*Form Number:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Individuals or households; Business or other for-profit entities; Not for profit institutions; State, Local or Tribal Government.

*Number of Respondents and Responses:* 335,979 respondents; 335,979 responses.

*Estimated Time per Response:* 15 minutes (.25 hours) to 30 minutes (.50 hours).

*Frequency of Response:* On occasion reporting requirement.

*Obligation to Respond:* Voluntary. The statutory authority for this collection is contained in 47 U.S.C. 208 of the Communications Act of 1934, as amended (the Act).

*Total Annual Burden:* 84,006 hours.

*Total Annual Cost:* None.

*Nature and Extent of Confidentiality:* Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB-1, "Informal Complaints, Inquiries and Requests for Dispute Assistance." As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB-1 "Informal Complaints, Inquiries, and Requests for Dispute Assistance," in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014.

*Privacy Impact Assessment:* The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at <http://www.fcc.gov/omd/privacyact/Privacy-Impact-Assessment.html>. The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the SORN.

*Needs and Uses:* The Commission consolidated all of the FCC informal consumer complaint intake into an online consumer complaint portal, which allows the Commission to better manage the collection of informal consumer complaints. Informal consumer complaints consist of informal consumer complaints, inquiries and comments. This revised information collection requests OMB approval for the addition of a layer of consumer reported complaint information related to the FCC's disability accessibility requirements for video programming digital apparatus and navigation device user interfaces (e.g., TV and set-top box controls, menus, and program guides). The information collection burdens associated with these complaints is being transferred from OMB Control Number 3060-1203 to OMB Control Number 3060-0874 to enable consumers to file complaints related to the Commission's user interfaces accessibility requirements through the Commission's online complaint portal.

Federal Communications Commission.  
**Marlene H. Dortch,**  
*Secretary, Office of the Secretary.*  
 [FR Doc. 2017-00884 Filed 1-13-17; 8:45 am]  
 BILLING CODE 6712-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0214]

### Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before February 16, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas\\_A\\_Fraser@omb.eop.gov](mailto:Nicholas_A_Fraser@omb.eop.gov); and

to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov). Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Cathy Williams at (202) 418-2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

#### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060-0214.

*Title:* Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 73.1212, 76.1701 and 73.1943, Political Files.

*Form Number:* None.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for profit entities; Not for profit institutions; State, Local or Tribal government; Individuals or households.

*Number of Respondents and Responses:* 24,013 respondents; 63,364 responses.

*Estimated Time per Response:* 1-52 hours.

*Frequency of Response:* On occasion reporting requirement, Recordkeeping requirement, Third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority that covers this information collection is contained in Sections 151, 152, 154(i), 303, 307 and 308 of the Communications Act of 1934, as amended.

*Total Annual Burden:* 2,087,626 hours.

*Total Annual Cost:* \$27,363.

*Privacy Impact Assessment:* The Commission prepared a system of records notice (SORN), FCC/MB-2, "Broadcast Station Public Inspection Files," that covers the PII contained in the broadcast station public inspection files located on the Commission's Web

site. The Commission will revise appropriate privacy requirements as necessary to include any entities and information added to the online public file in this proceeding.

*Nature and Extent of Confidentiality:* Most of the documents comprising the public file consist of materials that are not of a confidential nature. Respondents complying with the information collection requirements may request that the information they submit be withheld from disclosure. If confidentiality is requested, such requests will be processed in accordance with the Commission's rules, 47 CFR 0.459.

In addition, the Commission has adopted provisions that permit respondents subject to the information collection requirement for Shared Service Agreements to redact confidential or proprietary information from their disclosures.

*Needs and Uses:* The information collection requirements included under this OMB Control Number 3060-0214, requires commercial broadcast stations to maintain for public inspection a file containing the material set forth in 47 CFR 73.3526.

This collection is being revised to reflect the burden associated with the Shared Service Agreement disclosure requirements adopted in the *2014 Quadrennial Regulatory Review* (81 FR 76220, Nov. 1, 2016, FCC 16-107, rel. Aug. 25, 2016). The collection requires commercial television stations to place in their online public inspection file a copy of every Shared Service Agreement for the station (with the substance of oral agreements reported in writing), regardless of whether the agreement involves commercial television stations in the same market or in different markets, with confidential or proprietary information redacted where appropriate. For purposes of this collection, a Shared Service Agreement is any agreement or series of agreements in which (1) a station provides any station-related services, including, but not limited to, administrative, technical, sales, and/or programming support, to a station that is not directly or indirectly under common de jure control permitted under the Commission's regulations; or (2) stations that are not directly or indirectly under common de jure control permitted under the Commission's regulations collaborate to provide or enable the provision of station-related services, including, but not limited to, administrative, technical, sales, and/or programming support, to one or more of the collaborating stations. For purposes of this collection, the term "station" includes the licensee,

including any subsidiaries and affiliates, and any other individual or entity with an attributable interest in the station.

This information collection requirement will provide the Commission and the public with more comprehensive information about the prevalence and content of Shared Service Agreements between television stations, which will improve the Commission's and the public's ability to assess the potential impact of these agreements on the Commission's rules and policies.

The information collection requirements contained under 47 CFR 73.1212, 73.3527, 73.1943 and 76.1701 are still a part of the information collection and remain unchanged since last approved by OMB.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-00851 Filed 1-13-17; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice to All Interested Parties of the Termination of the Receivership of 10359—Community Central Bank, Mount Clemens, Michigan

*Notice Is Hereby Given* that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Community Central Bank, Mount Clemens, Michigan ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Community Central Bank on April 29, 2011. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be

considered which are not sent within this time frame.

Dated: January 10, 2017.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2017-00767 Filed 1-13-17; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meeting

**AGENCY:** Federal Election Commission

**DATE AND TIME:** Thursday, January 12, 2017 at the conclusion of the 10:00 a.m. open meeting.

**PLACE:** 999 E Street NW., Washington, DC.

**STATUS:** This meeting was closed to the public.

**ITEMS TO BE DISCUSSED:** Internal personnel rules and internal rules and practices.

\* \* \* \* \*

**PERSON TO CONTACT FOR INFORMATION:**

Judith Ingram, Press Officer, Telephone: (202) 694-1220.

**Dayna C. Brown,**

*Acting Secretary and Clerk of the Commission.*

[FR Doc. 2017-00967 Filed 1-12-17; 11:15 am]

**BILLING CODE 6715-01-P**

## FEDERAL RESERVE SYSTEM

### Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

**AGENCY:** Board of Governors of the Federal Reserve System.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board or Federal Reserve) is adopting a proposal to extend for three years, without revision the following reporting and recordkeeping requirements related to amendments made by the Gramm-Leach-Bliley Act, to the Bank Holding Company Act, the Federal Reserve Act, and related regulations. On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), to approve of and assign OMB numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB

inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452-3884. Telecommunications Device for the Deaf (TDD) users may contact (202) 263-4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shaguftha Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

**SUPPLEMENTARY INFORMATION:** The Board is adopting a proposal to extend for three years, without revision the following reporting and recordkeeping requirements related to amendments made by the Gramm-Leach-Bliley Act, to the Bank Holding Company Act, the Federal Reserve Act, and related regulations:

- The mandatory Declarations to Become a Financial Holding Company (FHC) (FR 4010);<sup>1</sup>
- The voluntary Requests for Determinations and Interpretations Regarding Activities Financial in Nature (FR 4011);
- The mandatory Notices of Failure to Meet Capital or Management Requirements (FR 4012);<sup>2</sup>
- The mandatory Notices by State Member Banks to Invest in Financial Subsidiaries (FR 4017);
- The mandatory Regulatory Relief Requests Associated with Merchant Banking Activities (FR 4019); and
- The mandatory Recordkeeping Requirements Associated with Merchant Banking Activities (FR 4023).

These collections of information are event-generated and as such, there are no formal reporting forms associated

<sup>1</sup> Savings and Loan Holding Companies (SLHCs) were added to the FR 4010 as a result of Regulation LL 12 CFR 238.65. (76 FR 56508) September 13, 2011.

<sup>2</sup> SLHCs were added to the FR 4012 as a result of Regulation LL 12 CFR 238.65. (76 FR 56508) September 13, 2011.



with them. In each case, the type of information required to be filed is described in the Board's regulations.

*Final approval under OMB delegated authority of the extension, without revision, of the following information collection:*

*Report Title:* Certain Filings Related to the GLB Act.

*Agency Form Number:* FR 4010, FR 4011, FR 4012, FR 4017, FR 4019, and FR 4023.

*OMB Control Number:* 7100-0292.

*Frequency:* On occasion.

*Respondent Type:* BHCs, SLHCs, foreign banking organizations, and state member banks.

*Estimated Annual Reporting Hours:* FR 4010: BHCs and SLHCs, 93 hours, Foreign banks, 4 hours; FR 4011: 50 hours; FR 4012: BHCs decertified as an FHC, 2 hours, FHCs back into compliance—BHC, 140 hours; FR 4017: 4 hours; FR 4019: Regulatory relief requests, 4 hours, Portfolio company notification, 2 hours; FR 4023: 1500 hours.

*Estimated Average Hours per Response:* FR 4010: BHCs and SLHCs, 3 hours, Foreign banks, 4 hours; FR 4011: 10 hours; FR 4012: BHCs decertified as an FHC, 1 hour, FHCs back into compliance—BHC, 10 hours; FR 4017: 4 hours; FR 4019: Regulatory relief requests, 1 hour, Portfolio company notification, 1 hour; FR 4023: 50 hours.

*Number of respondents:* FR 4010: BHCs and SLHCs, 31, Foreign banks, 1; FR 4011: 5; FR 4012: BHCs decertified as an FHC, 2, FHCs back into compliance—BHC, 14; FR 4017: 1; FR 4019: Regulatory relief requests, 4, Portfolio company notification 2; FR 4023: 30.

*Legal Authorization and Confidentiality:*

- FR 4010 is authorized by section 4(I)(1)(C) of the BHC Act (12 U.S.C. 1843(I)(1)(C)); section 10(c)(2)(H) of the Home Owners' Loan Act (12 U.S.C. 1467a(c)(2)(H)); section 8(a) of the International Banking Act (12 U.S.C. 3106(a)); sections 225.82 and 225.91 of the Board's Regulation Y (12 CFR 225.82, 225.91; and section 238.65 of the Board's Regulation LL (12 CFR 238.65)).

- FR 4011 is authorized by section 4(j) and (k) of the BHC Act (12 U.S.C. 1843(j)-(k)), and sections 225.88 and 225.89 of the Board's Regulation Y (12 CFR 225.88, 225.89).

- FR 4012 is authorized by section 4(I)(1) and 4(m) of the BHC Act (12 U.S.C. 1843(I)(1), (m)); section 10(c)(2)(H) of the Home Owners' Loan Act (12 U.S.C. 1467a(c)(2)(H)); section 8(a) of the International Banking Act (12 U.S.C. 3106(a)); sections 225.83 and

225.93 of the Board's Regulation Y (12 CFR 225.83, 225.93); and section 238.66(b) of the Board's Regulation LL (12 CFR 238.66(b)).

- FR 4017 is authorized by section 9 of the FRA (12 U.S.C. 335), and section 208.76 of the Board's Regulation H (12 CFR 208.76).

- FR 4019 is authorized by section 4(k)(7) of the BHC Act (12 U.S.C. 1843(k)(7)); sections 225.171(e)(3), 225.172(b)(4); and section 225.173(c)(2) of the Board's Regulation Y (12 CFR 225.171(e)(3), 225.172(b)(4), 225.173(c)(2)).

- FR 4023 is authorized by section 4(k)(7) of the BHC Act (12 U.S.C. 1843(k)(7)), and sections 225.171(e)(4) and 225.175 of the Board's Regulation Y (12 CFR 225.171(e)(4), 225.175).

The obligation to respond to the FR 4011 is voluntary (for requests to determine that an activity is financial in nature or to issue an advisory opinion that an activity is within the scope of an activity previously determined to be financial in nature) and required to obtain or retain benefits (for approvals to engage in an activity that is complementary to a financial activity). The obligation to respond to the FR 4010, FR 4017, and FR 4019 is required to obtain or retain benefits. The obligation to respond to FR 4012 and the obligation to comply with the recordkeeping requirements of the FR 4023 is mandatory.

The information collected on the FR 4010, FR 4011, FR 4017, and FR 4019 and information related to a failure to meet capital requirements on the FR 4012 is not generally considered confidential. Nevertheless, a respondent may request confidential treatment of information contained in these information collections in accordance with section (b)(4) or (b)(6) of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4), (b)(6)). Any request for confidential treatment of information must be accompanied by a detailed justification for confidentiality. Information related to a failure to meet management requirements on the FR 4012 is considered confidential and exempt from disclosure under section (b)(4), because the release of this information would cause substantial harm to the competitive position of the entity, and section (b)(8), if the information is related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions (5 U.S.C. 552(b)(4), (b)(8)).

Additionally, the records kept in accordance with the Recordkeeping Requirements Associated with Merchant

Banking Activities are retained by the respondent itself and the FOIA would only be implicated if the Board's examiners retained a copy of the records as part of an examination or supervision of a banking institution. In this case, the records would likely be exempt from disclosure under exemption (b)(8), for examination material. 5 U.S.C. 552(b)(8). In addition, the records may also be exempt under (b)(4) and (b)(6).

*Abstract: FR 4010.*

The BHC Act, and Regulations Y and LL specify the information to be included in a declaration.<sup>3</sup> In most cases, FHC declarations are filed in the form of a letter addressed to the appropriate Federal Reserve Bank.

An FHC declaration filed by a U.S. BHC must state that the BHC elects to become an FHC, must be signed by an authorized official or representative, and must provide the following information:

- The name and head office address of the BHC and of each depository institution controlled by the BHC (multi-tiered filers may file a single declaration, provided the name and head office address of each tiered company is listed.)
- a certification that the BHC and all depository institutions controlled by the BHC are well capitalized and well managed as of the declaration date
- the capital ratios (as of the close of the previous quarter for all relevant capital measures) for each depository institution the BHC controls

An FHC declaration filed by a U.S. SLHC must state that the SLHC elects to be treated as an FHC, must be signed by an authorized official or representative, and must provide the following information:

- The name and head office address of the SLHC and of each depository institution controlled by the SLHC (Multi-tiered filers may file a single declaration, provided the name and head office address of each tiered company is listed.)
- a certification that the SLHC and all depository institutions controlled by the SLHC are well capitalized and well managed as of the declaration date
- the capital ratios (as of the close of the previous quarter for all relevant capital measures) for each depository institution the SLHC controls

An FBO declaration filed by an FBO must state that the FBO elects to be treated as an FHC, must be signed by an authorized official or representative,

<sup>3</sup> 12 U.S.C. 1843(I)(1); 12 CFR 225.82, 238.65(b) and 225.91.



and must provide the following information:

- With respect to each foreign bank controlled by the FBO, the bank's risk-based capital ratios, amount of tier 1 capital, and total assets, as of the close of the most recent quarter and as of the close of the most recent audited reporting period
- a certification that each foreign bank controlled by the FBO is well-capitalized and well-managed
- a certification that all U.S. depository institutions controlled by the FBO are well capitalized and well managed as of the declaration date
- the capital ratios (as of the close of the previous quarter for all relevant capital measures) for each U.S. depository institution controlled by the FBO

#### FR 4011

Regulation Y specifies the information to be collected in connection with each type of request.<sup>4</sup> A request for a determination that an activity is financial in nature or incidental to a financial activity must be in writing and:

- Identify, define, and describe the activity and explain how the activity would be conducted,
- explain why the activity should be considered financial in nature or incidental to a financial activity; and
- include information supporting the request and any other information required by the Board.

A request for an advisory opinion that a specific activity is within the scope of activities previously determined to be financial in nature, or incidental to a financial activity, must be in writing and:

- Identify and describe the proposed activity or the proposed product or service,
- offer support for the desired interpretation, and
- include any other information requested by the Board.

An applicant seeking prior approval to engage in an activity that the applicant believes is complementary to a financial activity must submit a written request that:

- Identifies, defines, and describes the activity and explains how the activity would be conducted;
- identifies the financial activity to which the proposed activity would be complementary and provides information sufficient to support a finding that the proposed activity is complementary to the financial activity;

- describes the scope and relative size of the proposed activity, measured by the percentage of the FHC's projected revenues expected to be derived from, and assets associated with, the activity;
- discusses the risks the activity may reasonably be expected to pose to the safety and soundness of the FHC's depository institutions and to the financial system generally;
- describes the potential adverse effects, including potential conflicts of interest, decreased or unfair competition, or other risks, that the activity could cause, and the measures the FHC proposes to take to address those potential effects;
- describes the potential benefits to the public, such as greater convenience, increased competition, or gains in efficiency, the proposal may be reasonably expected to produce; and
- provides information about the FHC's financial and managerial resources and any other information requested by the Board.

#### FR 4012

Regulation Y provides that the notice must identify the noncompliant banking entity and the area of noncompliance. Regulation Y does not prescribe a format for such notices, however, they typically take the form of a letter.<sup>5</sup> Plans submitted to remediate capital and management deficiencies typically include the following:

- An explanation of the specific actions the FHC will take to correct all areas of noncompliance
- a schedule within which each action will be taken
- any other information the Board may require

#### FR 4017

Regulation H requires FR 4017 notices to be in the form of a letter with enclosures and to:<sup>6</sup>

- Describe the proposed transaction by which the bank would acquire the stake in the financial subsidiary;
- provide the name and head office address of the subsidiary;
- describe each current and proposed activity of the financial subsidiary and the legal authority for each activity;
- provide the capital ratios, as of the end of the most recent calendar quarter, for the bank and each of its depository institution affiliates;
- certify that the bank and each of its depository institution affiliates were well-capitalized at the close of the

- previous calendar quarter and as of the notice date;
- certify that the bank and each of its depository institution affiliates are well-managed as of the notice date;
- certify that the bank meets any applicable debt rating or alternative requirements and complies both before and after the transaction with the limit on the aggregate amount of assets held by the bank's financial subsidiaries; and
- describe the insurance activities, if the financial subsidiary will engage in insurance activities, to be conducted and identify each state in which the company holds an insurance license and the state insurance authority that issued the license.

#### FR 4019

Regulation Y requires requests for extension of the holding period for a merchant bank investment to include the following information:<sup>7</sup>

- The reasons for the request, including information addressing the factors the Board must consider in acting on such a request (including the costs and risks to the FHC of disposing of the investment, market conditions, the extent and history of the FHC's involvement in managing or operating the portfolio company, and the FHC's average holding period for its merchant banking investments)
- an explanation of the FHC's plan for divesting the investment

A notice of extended routine management or operation of a portfolio company can be in the form of a brief letter and must identify the portfolio company, the date on which the FHC first became involved in the routine management or operation of the portfolio company, the reasons for the FHC's involvement, the actions taken by the FHC to address the circumstances giving rise to its involvement, and an estimate of when the FHC anticipates ceasing routinely managing or operating the portfolio company.

#### FR 4023

The general policies and procedures that an FHC must establish with respect to merchant banking must be reasonably designed to:<sup>8</sup>

- Monitor, with respect to each investment and the entire portfolio, carrying and market values and performance;
- identify and manage market, credit, and other risks of such investments;
- identify and monitor terms and risks of transactions of companies in which

<sup>5</sup> 12 CFR 225.83(b)(1), 225.93(b)(1) and 238.66(b).

<sup>6</sup> 12 CFR 208.76.

<sup>7</sup> 12 CFR 225.172(b)(4).

<sup>8</sup> 12 CFR 225.175(a)(1).

<sup>4</sup> 12 CFR 225.88(b) and (e), and 225.89.

the FHC has merchant banking investments;

- ensure the corporate separateness of the FHC and the companies in which it has merchant banking investments;
- ensure compliance with sections 23A and 23B of the FRA, anti-tying statutes, Regulation Y, and any other applicable provisions of law.

*Current Actions:* On October 18, 2016, the Board published a notice in the **Federal Register** (81 FR 71730) requesting public comment for 60 days on the proposal to extend, without revision, the reporting and recordkeeping requirements related to amendments made by the Gramm-Leach-Bliley Act, to the Bank Holding Company Act, the Federal Reserve Act, and related regulations. The comment period for this notice expired on December 19, 2016. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, January 11, 2017.

**Robert deV. Frierson,**  
*Secretary of the Board.*

[FR Doc. 2017-00841 Filed 1-13-17; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 10, 2017.

*A. Federal Reserve Bank of Richmond* (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528. Comments can also be sent electronically to

*Comments.applications@rich.frb.org:*

1. *Southern National Bancorp of Virginia, Inc.*, McLean, Virginia; to acquire Eastern Virginia Bankshares, Inc., Glen Allen, Virginia, and thereby indirectly acquire EVB, Tappahannock, Virginia.

In connection with this application, Applicant also has applied to acquire additional shares of Southern Trust Mortgage LLC, Virginia Beach, Virginia, Eastern Virginia Bankshares, Inc., Glen Allen, Virginia and EVB, Tappahannock, Virginia, and thereby engage in lending activities pursuant to section 225.28(b)(1) or Regulation Y.

Board of Governors of the Federal Reserve System, January 11, 2017.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2017-00846 Filed 1-13-17; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL RESERVE SYSTEM

### Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

**AGENCY:** Board of Governors of the Federal Reserve System.

**SUMMARY:** Notice is hereby given of the final approval of a proposal to extend for three years, without revision, the intermittent survey of business (FR 1374; OMB No. 7100-0302) and to extend for three years, without revision, the domestic finance company report of consolidated assets and liabilities (FR 2248; OMB No. 7100-0005) by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the

respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

#### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Acting Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452-3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263-4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

*Final approval under OMB delegated authority of the extension for three years, without revision, of the following reports:*

1. *Report title:* Intermittent Survey of Business.

*Agency form number:* FR 1374.

*OMB control number:* 7100-0302.

*Frequency:* On occasion.

*Respondents:* Businesses and state and local governments.

*Estimated number of respondents:* 2,410.

*Estimated average hours per response:* 15 minutes.

*Estimated annual burden hours:* 1,825 hours.

*General Description of Report:* The survey data are used by the Federal Reserve to gather information specifically tailored to the Federal Reserve's policy and operational responsibilities. There are two parts to this event-generated survey. First, under the guidance of Federal Reserve economists, the Federal Reserve Banks survey business contacts as economic developments warrant. Currently, there are approximately 2,400 business respondents for each survey (about 200 per Reserve Bank); occasionally state and local government officials are called, in which case there are far fewer respondents. It is necessary to conduct these surveys to provide timely information to the members of the Board and to the presidents of the Reserve Banks. Usually, these surveys are conducted by Reserve Bank economists telephoning or emailing purchasing managers, economists, or other knowledgeable individuals at selected, relevant businesses. Reserve Bank staff may also use online survey tools to

collect responses to the survey. The frequency and content of the questions, as well as the entities contacted, vary depending on developments in the economy. Second, economists at the Board survey business contacts by telephone, inquiring about current business conditions. Board economists conduct these surveys as economic conditions require, with approximately ten respondents for each survey.

**Legal authorization and confidentiality:** The Board's Legal Division has determined that the Board is authorized to collect this information under sections 2A and 12A of the Federal Reserve Act (12 U.S.C. 225a and 263) and that respondent participation in the survey is voluntary. Although the names of the participating entities might be disclosed in the summary memo and the memo might contain information provided to the Board for internal use only, exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) may exempt this information from disclosure to the public. However, if the information collected on the FR 1374 does not meet these standards for confidentiality (for example if the information collected is already public), it would not be granted confidential treatment.

**Current Actions:** On October 3, 2016, the Federal Reserve published a notice in the **Federal Register** (81 FR 68018) requesting public comment for 60 days on the extension, without revision, of the FR 1374. The comment period for this notice expired on December 2, 2016. The Federal Reserve did not receive any comments.

**2. Report title:** Domestic Finance Company Report of Consolidated Assets and Liabilities.

**Agency form number:** FR 2248.

**OMB control number:** 7100-0005.

**Frequency:** Monthly, quarterly, and semi-annually.

**Respondents:** Domestic finance companies and mortgage companies.

**Estimated number of respondents:** 450.

**Estimated average hours per response:** Monthly, 20 minutes; quarterly, 30 minutes; Addendum, 10 minutes.

**Estimated annual burden hours:** 750 hours.

**General Description of Report:** The FR 2248 is collected monthly as of the last calendar day of the month from a stratified sample of finance companies. Each monthly report collects balance sheet data on major categories of consumer and business credit receivables and on major short-term liabilities. For quarter-end months (March, June, September, and December), additional asset and liability

items are collected to provide a full balance sheet. A supplemental section collects data on securitized assets. The data are used to construct universe estimates of finance company holdings, which are published in the monthly statistical releases Finance Companies (G.20) and Consumer Credit (G.19), in the quarterly statistical release Flow of Funds Accounts of the United States (Z.1), and in the *Federal Reserve Bulletin* (Tables 1.51, 1.52, and 1.55).

**Legal authorization and confidentiality:** The Board's Legal Division has determined that the FR 2248 is authorized by law pursuant to Section 2A of the Federal Reserve Act, 12 U.S.C. 225a. The obligation to respond is voluntary. Individual respondent data are confidential under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

**Current Actions:** On October 3, 2016, the Federal Reserve published a notice in the **Federal Register** (81 FR 68018) requesting public comment for 60 days on the extension, without revision, of the FR 2248. The comment period for this notice expired on December 2, 2016. The Federal Reserve did not receive any comments.

Board of Governors of the Federal Reserve System, January 11, 2017.

**Robert deV. Frierson,**

*Secretary of the Board.*

[FR Doc. 2017-00842 Filed 1-13-17; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-17-17BX]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

Understanding the Needs, Challenges, Opportunities, Vision and Emerging Roles in Environmental Health (UNCOVER EH)—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC)

#### Background and Brief Description

The environmental health (EH) workforce is an essential component of the public health workforce. According to recent health department surveys, EH professionals are employed at approximately 85% of local health departments, 81% of state health departments, and 30% of tribal health departments. Describing and characterizing the EH workforce is essential to identifying gaps in staffing, training, and ultimately ensuring EH professionals are prepared to meet future challenges. Because EH professionals play a crucial role in decreasing illness in our communities and protecting people from traditional and emerging environmental factors that may adversely affect human health, the workforce challenges facing this critical component of the public health system are a concern for public and community health. CDC's goal is to create a strong, sustained, and prepared EH workforce to meet today's challenges and improve the health and safety of all. In order to meet this goal, it is necessary to first

describe and characterize the EH workforce to assess their needs, challenges, and opportunities.

This is a one-time information collection designed to thoroughly describe the health department EH workforce on: (1) The current supply of EH professionals; (2) EH workforce demographics and professional roles; (3) gaps in current EH education and competencies and training needs; and (4) critical skills and resources needed to meet the evolving and emerging EH issues and challenges. This information will benefit the government and other entities by providing essential data to inform and support workforce

development activities and initiatives and understand areas of practice and where gaps may exist in capacity to address current EH issues and future challenges.

The survey will be offered to the estimated 20,000 EH professionals working within health departments. They will be enumerated and recruited by identifying a point of contact in each state, local, tribal, and territorial health department from whom a roster of EH professionals will be requested. A list of respondents and their business email addresses will be generated and used for recruitment and survey administration. Any contact information collected will

be related to the respondents' role in the organization. Participation will be voluntary. We expect approximately 80 percent of the estimated 20,000 EH professionals (16,000 respondents) to respond to the survey.

Data will be collected one time from a census of members of the public health department EH workforce using a web-based survey instrument. The UNCOVER EH Survey will take approximately 30 minutes to complete per respondent. There will be no cost to respondents other than their time. The requested time burden is 8,269 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Health Department EH Administrative Staff ...	Health Department Roster .....	3,231	1	5/60
Health Department EH Professionals .....	UNCOVER EH Survey .....	16,000	1	30/60

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2017-00815 Filed 1-13-17; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-17-17KB; Docket No. CDC-2017-0002]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection titled "Assessment of the Market for Electronic Technology for

Underground Coal Mining Safety and Health Applications." From this information collection project, NIOSH seeks to provide insight into what the most important barriers are from the perspective of the organizations that must purchase, use, approve, and manufacture these safety technologies.

**DATES:** Written comments must be received on or before March 20, 2017.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2017-0002 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for

Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital

or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

Assessment of the Market for Electronic Technology for Underground Coal Mining Safety and Health Applications—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Underground coal mining in the U.S. is a relatively small industry (about 46,000 employees) that operates in a unique and hazardous work environment. The common presence of explosive gasses and other hazards creates special safety requirements for equipment, including safety and health protection technologies, used in

underground coal mines. This request is for a 2-year approval period.

The MINER Act of 2006 assigned the National Institute for Occupational Safety and Health (NIOSH) the responsibility to enhance development of new mine safety and health protection technology and technological applications and to expedite the commercial availability and implementation of such technology. As part of this study, NIOSH seeks to identify the barriers to commercial availability and implementation of such technology in U.S. mines.

Experience to date has shown that there are many issues that the U.S. mining industry faces that create barriers to the availability and implementation of safety technologies, and we believe there are other more subtle reasons that we do not fully understand as a Government research agency. The data are intended to provide insight into what the most important barriers are from the perspective of the organizations that must purchase, use, approve, and manufacture these safety technologies.

NIOSH has an understanding of some of these barriers, however NIOSH is not an end user of these products. Thus the goal of the study is to provide a complete perspective of the barriers from the point of view of the mine operators and technology innovators, in order to improve the efficacy of the contract and grant awards that NIOSH administers under the authority of the MINER Act.

The Federal Mine Safety & Health Act of 1977, Section 501 authorizes the

collection of this data. A CDC contractor will collect the required data.

NIOSH will identify 200 stakeholder organizations for structured interviews. Stakeholder organizations include those parties involved in the development, supply, use, and regulation of safety and health protection technologies relevant to underground coal mining. Because there is no nationally representative database of these stakeholder organizations, NIOSH will use web searches of supplier and mining company Web sites, online mining publications, trade association member directories, federal and state regulator Web sites, and university mining research and development programs to compile a list of 200 organizations. Representatives of NIOSH Office of Mining Safety and Health Research will also augment the search with their input.

Of the 200 stakeholder organizations, we expect to elicit participation from 100 and conduct 150 interviews (up to 2 interviews per organization).

A pre-call to each organization is expected to require 15 minutes to complete and the structured interview is expected to require 60 minutes to complete; including the time it may take respondents to look-up and retrieve needed information.

In addition, the workshop will be held in-person and last for nine hours. An average of six hours of travel is estimated for participants in the workshop. The estimated annualized burden hours for the respondents' time to participate in this information collection is 650 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Receptionists .....	Pre-Call .....	200	1	15/60	50
General and Operational Managers .....	Structured Interview .....	75	1	60/60	75
Industrial Production Managers .....	.....	38	1	60/60	38
Architecture and Engineering Occupations ....	.....	37	1	60/60	37
General and Operations Managers .....	Workshop .....	15	1	15	225
Industrial Production Managers .....	.....	8	1	15	120
Architecture and Engineering Occupations ....	.....	7	1	15	105
<b>Total .....</b>	.....	.....	.....	.....	<b>650</b>

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.

[FR Doc. 2017-00833 Filed 1-13-17; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-3070G-I and CMS-R-38]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by February 16, 2017.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number,

and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:**

Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* ICF/IID Survey Report Form and Supporting Regulations; *Use:* The information collected with forms 3070G-I is used to determine the level of compliance with Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) CoPs necessary to participate in the Medicare/Medicaid program. Information needed to monitor the State's performance as well as the ICF/IID program in general, is available to CMS only through the use of information abstracted from the survey report form. The form serves as a coding worksheet designed to facilitate data entry and retrieval into the Automated Survey Processing Environment Suite (ASPEN) in the State and at the CMS regional offices. *Form Number:* CMS-3070G-I (OMB control number: 0938-0062); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 6,310; *Total Annual Responses:* 6,310; *Total Annual Hours:* 18,930. (For policy questions regarding this collection contact Melissa Rice at 410-786-3270.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of*

*Information Collection:* Conditions for Certification for Rural Health Clinics; *Use:* The Rural Health Clinic (RHC) conditions of certification are based on criteria prescribed in law and are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients. We use these conditions of participation to certify RHCs wishing to participate in the Medicare program. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing and the American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number:* CMS-R-38 (OMB control number: 0938-0334); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 4,247; *Total Annual Responses:* 4,247; *Total Annual Hours:* 18,284. (For policy questions regarding this collection contact Jacqueline Leach at 410-786-4282.)

Dated: January 11, 2017.

**William N. Parham, III,**  
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017-00863 Filed 1-13-17; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10638]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are

invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by March 20, 2017.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10638 PRA for Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective

**Payment System**

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* PRA for Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective Payment System; *Use:* Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. We

use the application in order to determine if a technology meets the new technology criteria. *Form Number:* CMS-10638 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households, Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 600. (For policy questions regarding this collection contact Noel Manlove at 410-786-5161.)

Dated: January 11, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017-00860 Filed 1-13-17; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities: Proposed Collection; Public Comment Request; Protection and Advocacy for Traumatic Brain Injury (PATBI) Program Performance Report**

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow 60 days for public comment on the proposed action. This notice collects comments on the information collection requirements relating to an existing collection previously in use without an OMB Control Number: Protection and Advocacy for Traumatic Brain Injury (PATBI) Program Performance Report.

**DATES:** Submit written comments on the collection of information by March 20, 2017.

**ADDRESSES:** Submit written comments on the collection of information by email to [wilma.roberts@acl.hhs.gov](mailto:wilma.roberts@acl.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Wilma Roberts, Administration for Community Living, Administration on Intellectual and Developmental



Disabilities, Office of Program Support, 330 C Street SW., Washington, DC 20201, 202-795-7449.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, ACL is publishing a notice of the proposed collection of information set forth in this document. The Children's Health Act of 2000, 42 U.S.C. Section 300d-53(h), requires the Protection and Advocacy (P&A) System in each State to annually prepare and submit to the Secretary a report that includes documentation of the progress they have made in serving individuals with traumatic brain injury. AIDD will review the program performance report (PPR) for compliance and for program outcomes. AIDD will aggregate the information in the PPRs into a national profile of programmatic activities and accomplishments. Information from these reports is shared with the public through postings to the *ACL.gov* Web site. The information will also allow AIDD to track accomplishments against performance goals and determine areas where technical assistance is needed to comply with Federal requirements or improve performance.

The proposed Protection and or Traumatic Brain Injury (PATBI) Program Performance Report (PPR) form can be found on the AIDD Web site at: [https://acl.gov/Programs/AIDD/Program\\_Resource\\_Search/Results\\_PA.aspx](https://acl.gov/Programs/AIDD/Program_Resource_Search/Results_PA.aspx).

Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

ACL estimates the burden hours for this collection of information as follows:

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PATBI PPR .....	57	1	16	912

Dated: January 10, 2017.  
**Edwin Walker,**  
*Acting Administrator and Assistant Secretary for Aging.*  
 [FR Doc. 2017-00879 Filed 1-13-17; 8:45 am]  
**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration on Community Living**

**Proposed Information Collection Activity; Submission for OMB Review; Comment Request; Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities**

**AGENCY:** Office of Program Support, Administration on Intellectual and Developmental Disabilities, Administration on Disability, Administration on Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Disability is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as

required under the Paperwork Reduction Act of 1995.  
**DATES:** Submit written comments on the collection of information by February 16, 2017.

**ADDRESSES:** Submit written comments on the collection of information by fax 202.395.5806 or by email to *OIRA\_submission@omb.eop.gov*, Attn: OMB Desk Officer for ACL.

**FOR FURTHER INFORMATION CONTACT:** Clare Huerta, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, 330 C Street SW., DC, Washington, DC 20201, by email: *Clare.Huerta@acl.hhs.gov* or by phone: (202) 795-7301.

**SUPPLEMENTARY INFORMATION:** In compliance with section 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

This notice seeks to collect comments on revisions to two existing data collections. The first is the Annual Protection and Advocacy Systems Program Performance Report (0985-0027). State Protection and Advocacy (P&A) Systems in each State and Territory provide individual legal advocacy, systemic advocacy,

monitoring and investigations to protect and advance the rights of people with developmental disabilities, using funding administered by the Administration on Intellectual and Developmental Disabilities, Administration on Disability, Administration on Community Living, HHS. The Developmental Disabilities and Bill of Rights Act (the Act), 42 U.S.C. 15044 requires each P&A to annually prepare a Program Performance Report (PPR) that describes the activities and accomplishments of the system during the preceding fiscal year.

The Act also requires P&As to submit a Statement of Goals and Priorities (SGP) (0985-0034) for each coming fiscal year. P&As are required to annually report on "the activities, accomplishments, and expenditures of the system during the preceding fiscal year, including a description of the system's goals, the extent to which the goals were achieved, barriers to their achievement, the process used to obtain public input, the nature of such input, and how such input was used."

To meet its statutory reporting requirements, P&As have used separate forms for submitting the annual PPR (0985-0027) and the SGP (0985-0034). The Department is proposing that the

two be combined by creating a Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities form. By combining the forms, P&As will have a reduced burden because they will only have to submit one annual report. The combined form will also allow federal reviewers to analyze patterns more readily between goals and priority setting and program performance.

The annual PPR and SGP are reviewed by federal staff for compliance and outcomes. Information in the PPRs and SGPs is analyzed to create a national profile of programmatic compliance, outcomes, and goals and priorities for P&A Systems for tracking accomplishments against goals and to formulate areas of technical assistance related to compliance with Federal requirements and program performance. Information collected in the unified report will inform AIDD of trends in

P&A advocacy, collaboration with other federally-funded entities, and identify best practices for efficient use of federal funds.

**Comments in Response to the 60 Day Federal Register Notice**

A notice was published in the **Federal Register** in Vol. 81, No. 57592 on August 23, 2016, announcing that ACL was requesting approval of a data collection (ICR New). ACL received two comments expressing concern that the combination of the SGP and PPR reporting forms would reduce the overall oversight of the P&A program. ACL responds that, while the reporting forms are being combined, the content which the grantees are reporting remains the same, with the addition of more quantitative measures to support the qualitative data that the grantees provide every year. The addition of more quantitative measures will provide a fuller picture of how the programs are

functioning. The combined PPR and SGP allow federal staff to review the same information from the programs in a streamlined format that reduces the need to reenter the same information multiple times. ACL does not plan to make any changes in the data collection based on these comments.

**SUPPLEMENTARY INFORMATION:** In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living is soliciting public comment on the burden related to the information collection described above. *The form is available at: [http://www.acl.gov/Programs/AIDD/Program\\_Resource\\_Search/Results\\_PA.aspx](http://www.acl.gov/Programs/AIDD/Program_Resource_Search/Results_PA.aspx).*

*Estimated Burden:* The average burden for the 57 Protection and Advocacy Systems<sup>1</sup> was calculated based on consultations with selected States.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities .....	57	1	75	4,275

*Estimated Total Annual Burden Hours: 4,275.*

Dated: January 10, 2017.

**Edwin L. Walker,**  
*Acting Administrator and Assistant Secretary for Aging.*

[FR Doc. 2017-00880 Filed 1-13-17; 8:45 am]

**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-D-4412]

**Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an Abbreviated New Drug Application; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled

“Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.” This draft guidance is intended to assist potential applicants who plan to develop and submit an abbreviated new drug application (ANDA) to seek approval of a generic combination product that includes both a drug constituent part and a delivery device constituent part.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance March 20, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food

<sup>1</sup>This number includes the 50 States, District of Columbia, Puerto Rico and three Outlying Areas.

and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2016–D–4412 for “Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts

and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Andrew LeBoeuf, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0503, [Andrew.LeBoeuf@fda.hhs.gov](mailto:Andrew.LeBoeuf@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.”

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) created, among other things, section 505(j) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Under section 505(j) of the FD&C Act, an ANDA applicant can rely on FDA’s previous finding that the reference listed drug (RLD) is safe and effective so long as the ANDA applicant demonstrates that the proposed drug product and the RLD are the same with respect to active ingredient(s), dosage form, route of administration, strength, and, with certain exceptions, labeling. An ANDA must also include sufficient information to demonstrate that the proposed product is bioequivalent to the RLD, and that the ANDA meets the approval requirements relating to chemistry, manufacturing, and controls. An ANDA generally is not required to be the same as the listed drug it references in certain respects. For example, a generic drug generally can differ from its RLD in certain respects with regard to the device or with respect to inactive ingredients.

Drug products that meet the approval requirements under section 505(j) of the FD&C Act are generally considered by FDA to be therapeutically equivalent to their RLD. Products classified as therapeutically equivalent can be

substituted with the full expectation that the generic product will produce the same clinical effect and safety profile as the RLD under the conditions specified in the labeling.

These general principles apply to products submitted in ANDAs, including drug-device combination products. A generic drug-device combination product classified as therapeutically equivalent to the RLD can be expected to produce the same clinical effect and safety profile as the RLD under the conditions specified in labeling. This does not mean, however, that the proposed generic drug-device combination product and its RLD need to be identical in all respects. FDA recognizes that an identical design may not always be feasible and, in certain instances, differences in the design of the user interface for a generic drug-device combination product as compared to the RLD may exist without precluding approval of the generic combination drug-device product under an ANDA. In some instances in which differences exist, certain additional information and/or data relating to the user-interface of the proposed generic drug-device combination product, such as data from comparative use human factors studies, may be appropriate to support approval of the proposed product in an ANDA. The extent to which differences between the proposed product and the RLD affect the approvability of the proposed ANDA product will be evaluated on a case-by-case basis.

This draft guidance provides general principles, including recommendations on threshold analyses, which are intended to assist potential applicants in the identification and the assessment of differences in the design of the user interface of a proposed generic drug-device combination product when compared to the user interface for its RLD.

This draft guidance also provides recommendations on the design and conduct of comparative use human factors studies that may help applicants determine whether design differences identified between the proposed generic drug-device combination product and its RLD would preclude approval as an ANDA under the FD&C Act.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.” It does not establish any rights for any

person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 10, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00795 Filed 1-13-17; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-0121]

#### Compliance Policy for Required Warning Statements on Small-Packaged Cigars; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Compliance Policy for Required Warning Statements on Small-Packaged Cigars.” The draft guidance, when finalized, is intended to assist any person who manufactures, packages, sells, offers to sell, distributes, or imports cigars in small packages, in complying with the warning statement requirements in FDA’s regulations deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance describes FDA’s compliance policy for cigars in packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements. The draft guidance explains that FDA does not intend to take enforcement action with respect to cigars that do not comply with the size and placement requirements in the regulation when the information and specifications required under the regulation appear on the carton or other outer container or wrapper that could accommodate the required warning statements, or on a tag otherwise firmly and permanently affixed to the cigar package.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2017-D-0121 for “Compliance Policy for Required Warning Statements on Small-Packaged Cigars.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly

viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Deirdre Jurand, Center for Tobacco

Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Compliance Policy for Required Warning Statements on Small-Packaged Cigars."

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28974). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act, which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of the public health." The rule specifies the health warning statements that must be displayed on cigar packaging and where those statements must be placed, among other requirements.

The draft guidance discusses FDA's compliance policy for cigars with packaging too small or otherwise unable to accommodate the warning statements and specifications required under the regulation.

### II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on its compliance policy for cigars in small packaging. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### III. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 1143 have been approved under 0910-0768.

### IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00855 Filed 1-13-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-0120]

#### Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops." This draft guidance provides FDA's interpretation of, and a compliance policy for, the requirement that the label of tobacco products contain an accurate statement of the percentage of foreign and domestic grown tobacco under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This draft guidance document is also intended to assist retailers who sell newly deemed products by explaining whether engaging in certain activities subjects such establishments to additional requirements of the FD&C Act and the limited circumstances under which FDA does not intend to enforce compliance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency

considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2017-D-0120 for "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov>

or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Katherine Collins, Center for Tobacco Products, Food and Drug

Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

We are announcing the availability of a draft guidance for industry entitled “Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.”

This draft guidance document, when finalized, will provide FDA’s interpretation of, and a compliance policy for, the label requirement under section 903(a)(2)(C) of the FD&C Act (21 U.S.C. 387c(a)(2)(C)). This draft guidance document, when finalized, is also intended to assist retailers who sell newly deemed products by explaining whether engaging in certain activities subjects such establishments to additional requirements of the FD&C Act and the limited circumstances under which FDA does not intend to enforce compliance.

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amends section 904 of the FD&C Act (21 U.S.C. 387d) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA’s tobacco product authorities in chapter IX of the FD&C Act, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Under that authority, FDA issued a rule deeming all other products that meet the statutory definition of “tobacco product,” set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except for accessories of those products, as subject to chapter IX of the FD&C Act (81 FR 28974). FDA published the final rule on May 10, 2016, and it became effective on August 8, 2016.

Section 903(a)(2)(C) of the FD&C Act provides that a tobacco product in package form is misbranded unless its label contains “an accurate statement of the percentage of tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco.” The draft

guidance provides FDA’s interpretation of, and a compliance policy for, this label requirement.

Retail establishments, such as vape shops, which engage in certain activities may also be subject to certain requirements of the FD&C Act that apply to tobacco product manufacturers and to establishments that engage in the manufacture, preparation, compounding, or processing of tobacco product. These activities may also include modifying a product so that it is a new tobacco product requiring compliance with the premarket authorization requirements. This draft guidance explains which activities subject vape shops to these FD&C Act requirements and the limited circumstances under which FDA does not intend to enforce compliance.

**II. Significance of Guidance**

FDA is issuing this draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the draft guidance at either <https://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: January 9, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–00773 Filed 1–13–17; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–D–0114]

**Referencing Approved Drug Products in Abbreviated New Drug Application Submissions; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled

“Referencing Approved Drug Products in ANDA Submissions.” Any person is permitted to submit an abbreviated new drug application (ANDA) in order to seek approval to market a generic version of a previously approved drug product. The purpose of this guidance is to provide information to potential applicants on how to identify a reference listed drug (RLD), reference standard, and the basis of submission in an ANDA submission.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 20, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments,

except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2017-D-0114 for “Referencing Approved Drug Products in ANDA Submissions.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New

Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Gail Schmerfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-9291, [gail.schmerfeld@fda.hhs.gov](mailto:gail.schmerfeld@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Referencing Approved Drug Products in ANDA Submissions.” To obtain approval of an ANDA submitted under section 505(j) of the FD&C Act (21 U.S.C. 355(j)), an ANDA applicant generally must show, among other things, that the proposed generic drug has the same active ingredient(s), conditions of use, route of administration, dosage form, strength, and, with certain permissible differences, labeling as the specific listed drug referred to in the ANDA, *i.e.*, the RLD. Under section 505(j)(2)(A)(iv) of the FD&C Act, the ANDA applicant also must demonstrate that the proposed generic drug is bioequivalent to the RLD and, if in vivo bioequivalence studies are required for approval of the ANDA, the applicant must use the reference standard selected by FDA in such testing (21 CFR 314.3(b)). Further, under section 505(j)(2)(A)(vi) of the FD&C Act, a generic drug must meet the same high standards of quality and manufacturing as drug products approved under section 505(c) of the FD&C Act.

This guidance provides information to potential applicants on how to identify a “reference listed drug,” “reference standard,” and the “basis of submission” in ANDA submissions. A variety of factors has led to confusion among stakeholders on what these terms mean and how an ANDA applicant should use them. These factors include the discontinued marketing of many approved drug products and FDA’s identification of reference standards with the RLD symbol (“+”) in the printed version, and under the “RLD” column in the electronic version, of FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”). This guidance is intended to address this confusion by explaining what these terms mean and clarifying the differences among them. This guidance provides



recommendations on how to accurately use these terms in an ANDA, how persons can request FDA designation of an RLD, and how persons can request FDA selection of a reference standard.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Referencing Approved Drug Products in ANDA Submissions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00820 Filed 1-13-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-4662]

#### **Public Hearing: Strategic Partnerships To Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing a public hearing regarding FDA initiatives for enhancing the safety of foods (for humans and animals) imported into the United States. The hearing will focus on partnerships to improve safety capabilities through capacity building; partnerships that incorporate information from private entities and foreign competent authorities to inform risk-based decisionmaking; partnerships that recognize commodity-specific export programs; and partnerships that recognize the robustness of a nation's entire food safety system. In addition, we are seeking information from a

variety of viewpoints, including from competent authorities in other countries and from private entities, to help inform FDA regarding risk-based decisionmaking, commodity-specific export control programs in other countries, and systems recognition.

**DATES:** See "How to Participate in the Hearing" in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, closing date to submit comments to the docket, and other information regarding meeting participation.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2016-N-4662 for "Public Hearing: Strategic Partnerships to Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Wade Woolfolk, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-550), 5001

Campus Dr., College Park, MD 20740, 240-402-6411, FAX: 301-436-2618, email: [wade.woolfolk@fda.hhs.gov](mailto:wade.woolfolk@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

On March 30–31, 2011, we held a public hearing to discuss our use of international comparability assessments as a mechanism to help enhance the safety of imported foods (see “Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries; Public Hearing; Request for Comments” (76 FR 13638, March 14, 2011; available at <https://www.regulations.gov>, in docket FDA–2011–N–0135)). At the public hearing we presented information on our food safety capacity building efforts related to the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). We also held a public meeting on June 19, 2012, to discuss our comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States (see “International Capacity Building with Respect to Food Safety Public Meeting” (77 FR 30017, May 21, 2012; available at <https://www.regulations.gov>, in docket FDA–2011–N–0135)). This meeting invited discussion on the International Capacity Building plan development under FSMA. Following these discussions we issued the final International Capacity Building Plan in February 2013. See <http://www.fda.gov/food/guidanceregulation/fsma/ucm301708.htm>.

FSMA has enabled us to better protect public health through new authorities to help ensure that imported foods meet the same safety standards as foods produced in the United States.

In implementing FSMA, we recognize the importance of strengthening the existing collaborations among food safety regulators (U.S. Federal, State, local, territorial, tribal, and foreign) to achieve our public health goals. We continue to engage in a variety of partnerships that, collectively, are intended to enhance the safety of foods imported into the United States.

At the public hearing that is the subject of this notice, we will provide an update on our food safety capacity building efforts, as well as additional updates and information on the approach we will use to help ensure the safety of imported foods. In addition, the public hearing will provide an opportunity for FDA to obtain testimony from diverse stakeholder groups as we

seek to develop, expand, or refine key partnership activities.

We seek input from a variety of perspectives on the following topics:

- How to expand performance measurement for FDA’s capacity building activities to ensure that we collaborate effectively with other nations, multilateral organizations, donor organizations, and industry.
- How to operationalize the concept of “same level of public health protection” that is part of the rule on Foreign Supplier Verification Programs (FSVP) (80 FR 74226, November 27, 2015) and what types of partnerships facilitate application of this concept. (The FSVP regulation requires importers to implement FSVPs to provide adequate assurances that the importer’s foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.)

- Whether and how we should consider private standards in risk-based decisionmaking, including how other competent authorities use information, such as third-party certifications or other assurances, from private entities.

- Whether and how we should expand our systems recognition framework to include consideration of the recognition of commodity-specific export control programs.

The initiatives that will be discussed at the public hearing align with and support FSMA implementation. Day one of the hearing will seek input on partnerships to improve food safety capabilities in other countries, tools to inform FDA’s risk based decisionmaking, and methods to assess the effectiveness of our capacity building efforts. We also seek input on whether and how best to incorporate input from private entities and other competent authorities into our risk-based decisionmaking framework. Day two will seek input on partnerships that recognize the robustness of commodity-specific export programs including export certification programs and whether and how we should consider such programs. In addition, we seek input on the implementation of the systems recognition program. Interested parties may submit comments, data, and

supporting information on the issues described in part II of this document.

## II. Purpose and Format of the Public Hearing

### A. Day One of Hearing

#### 1. Partnerships To Improve Food Safety Capabilities: International Capacity Building

Section 305 of FSMA requires the Secretary of Health and Human Services to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States. This authority was delegated to FDA, and we developed an International Food Safety Capacity Building Plan (the Plan). The Plan gives us a strategic framework to expand the technical, scientific, and regulatory capacity of foreign governments and their food industries. We developed the Plan in consultation with many partners, such as officials from other parts of the U.S. government; foreign government officials; non-governmental organizations (NGOs) that represent consumer interests; food industry representatives; and others. We seek input on successful models for continuing capacity building to further implement the plan. At this hearing, we will seek comment on food safety capacity building and development and invite comment, particularly publications and data, on food safety performance monitoring regimes; how donor organizations minimize duplication and support leveraged partnerships; how providers of training programs assure affordable, accessible, and culturally specific information is available to various regions of the world; how development agencies interface with food industry supply chain management programs; and whether we and industry can leverage each other’s efforts.

#### 2. Partnerships To Incorporate Information From Competent Authorities and Private Entities To Inform Risk-Based Decisionmaking

In the **Federal Register** of November 27, 2015 (80 FR 74570), we published a final rule entitled, “Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications.” The final rule established a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits of foreign food facilities and to issue food and facility certifications. The requirements in the final rule will help

ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program. We are aware that other countries incorporate information from private entities into their regulatory decisionmaking. We are interested in learning more about the policies, practices, and programs used by foreign regulators to ensure the safety of food imported into their countries. We seek comment and examples on how other countries use information from private entities; how other countries ensure parity in audit, inspectional, verification, and overall oversight between domestic and import activities; and how transparency can be best achieved.

*B. Day Two of Hearing*

1. Partnerships That Recognize Commodity-Specific Exports and Programs

We are interested in identifying successful models that recognize commodity specific food safety control systems (including export certification programs), how they are established, and how they operate.

We seek comment and views on the best practices, strengths and weaknesses of commodity export programs or export certification systems; how commodity recognition programs factor into risk-based inspectional systems; and once adopted, how the programs are monitored over time.

2. Partnerships That Recognize the Robustness of the Entire Food Safety System: Systems Recognition

FDA's systems recognition assessment process established in 2011 has progressed from a pilot to a robust program that has resulted in signed

arrangements with New Zealand's Ministry for Primary Industries (2012) and Canada's Canadian Food Inspection Agency (CFIA) and the Department of Health Canada (Health Canada) (2016). We seek comment on what indicators we should consider to determine whether the program meets expected outcomes and best practices on how to identify robust food safety systems.

**III. Notice of Hearing Under Part 15**

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer(s), accompanied by FDA senior management and staff from the relevant centers/offices (FDA panelists/experts).

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. We encourage interested parties to submit comments to the docket. We also have invited certain members of the public to participate as guest presenters. Only the presiding officer(s) and FDA panelists/experts may question any person during or at the conclusion of each presentation by the FDA and guest presenters (§ 15.30(e)). At their discretion, the presiding officer(s) may permit questions to be submitted from the audience for response by FDA or other persons attending the hearing (§ 15.30(e)). Finally, time permitting, stakeholders may be allowed to provide testimony at the hearing. Time will be limited to 2 minutes and requests to make an oral presentation must be written and received by February 8, 2017. Please include the details of your presentation when making your request. All testimony will be entered into the docket. Public hearings under part 15

are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see part IV of this document). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Comments may also be submitted after the hearing. The docket will remain open for such comments until May 16, 2017.

**IV. How To Participate in the Public Hearing**

Advance registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis.

Notices of participation may be submitted electronically (see table 1 of this document); FDA encourages the use of electronic means of advance registration. Notices of participation may also be submitted orally or by mail, fax, or email (see **FOR FURTHER INFORMATION CONTACT**). See table 1 of this document for the dates by which notices of participation must be submitted. A single copy of any notice of participation is sufficient.

Table 1 of this document provides information on participation in the public meetings.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

Activity	Date	Electronic address	Address	Other information
Attend Public Hearing .....	February 14–15, 2017, from 9 a.m. to 5:00 p.m.	Please preregister at <a href="http://www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm">www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm</a> .	FDA Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Dr., College Park, MD 20740.	Registration check-in begins at 8 a.m.
View Webcast .....	February 14–15, 2017, from 9 a.m. to 5:00 p.m.	Individuals who wish to participate by Webcast are asked to preregister at <a href="http://www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm">www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm</a> .	We encourage you to use electronic registration if possible.	The Webcast will have closed captioning.
Advance registration .....	Register by February 8, 2017.	<a href="http://www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm">www.fda.gov/Food/NewsEvents/Workshops/Meetings/Conferences/default.htm</a> .	We encourage you to use electronic registration if possible <sup>1</sup> .	There is no registration fee for the public hearing. Early registration is recommended because seating is limited. <sup>1</sup>

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING—Continued

Activity	Date	Electronic address	Address	Other information
Request to make an oral presentation.	Request by February 8, 2017.	Individuals who wish to make a public comment during the designated times in the hearing are asked to submit request and presentation at <a href="mailto:IASEvents@fda.hhs.gov">IASEvents@fda.hhs.gov</a> .	See <b>FOR FURTHER INFORMATION CONTACT</b> .	
Submitting either electronic or written comments.	Submit all other comments by May 16, 2017.	<a href="https://www.regulations.gov">https://www.regulations.gov</a>	Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See <b>ADDRESSES</b> for information on submitting comments.
Request special accommodations due to a disability.	Request by February 8, 2017.	Wade Woolfolk, email: <a href="mailto:wade.woolfolk@fda.hhs.gov">wade.woolfolk@fda.hhs.gov</a> .	See <b>FOR FURTHER INFORMATION CONTACT</b> .	

<sup>1</sup> Onsite registration will not be available at the meeting site.

## V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on FDA's Web site at <http://www.fda.gov>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00821 Filed 1-13-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Hospital Organ Donation Campaign's Activity Scorecard

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first

public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than February 16, 2017.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* National Hospital Organ Donation Campaign's Activity Scorecard OMB No. 0915-0373—Revision.

*Abstract:* HRSA's Healthcare Systems Bureau, Division of Transplantation, administers the Workplace Partnership for Life (WPFL) program under the authority of Section 377A(a) of the Public Health Service (PHS) Act, (42 U.S.C. 274f-1). The WPFL seeks to involve workplaces and other organizations in a national effort to increase the number of registered organ, eye, and tissue donors and to increase awareness about organ donation. In 2011, HRSA launched the National Hospital Organ Donation Campaign (Hospital Campaign) and issued a challenge to hospitals nationwide to assist in this effort by conducting donor education and donor registry enrollment events in their hospitals and communities. The nation's 58 organ procurement organizations (OPOs), which already work with hospitals on

clinical aspects of transplantation, participate in the Hospital Campaign to provide assistance to hospitals in their service areas as they implement strategies and activities to increase the number of enrollments in state donor registries. HRSA supports the Hospital Campaign by providing communications materials, facilitating the sharing of best practices, leveraging the influence of national associations and organizations related to hospitals and organ donation as Campaign National Partners, and offering the additional incentive of national-level recognition to hospitals.

Need and Proposed Use of the Information: The Hospital Campaign's Activity Scorecard is a key component of this effort. It provides a menu of over 40 ideas for outreach activities. The Activity Scorecard also provides incentive for hospitals to participate by laying the foundation for recognition. Each activity on the programmable PDF is assigned a particular number of points based on the activity's potential for generating registrations. Recognition is awarded to hospitals that have annual points which qualify them for one of the following recognition levels: bronze, silver, gold, and platinum.

Hospitals can complete the Activity Scorecard and submit it annually via email or fax to HRSA or to their local OPO or Donate Life America (DLA) affiliate to be considered for recognition. This is a voluntary activity and hospitals may participate in the campaign without using or submitting a completed Activity Scorecard. However, most hospitals enrolled in the campaign (currently 2,038) have submitted a completed Activity Scorecard to become eligible for recognition.

Hospitals that achieve specific outlined levels are recognized annually

in several ways: By receipt of a HRSA certificate of recognition presented to hospitals by their participating OPOs in various ceremonies; by HRSA's sharing of a consolidated list of recognized hospitals during the final webinar of the project year that occurs after scorecard submission; in the final e-newsletter of the project year; and in communications sent out by the campaign's 11 national partners, which include the American Hospital Association, the Association of Organ Procurement Organizations, and the American Society of Transplant Surgeons. Hospitals also frequently distribute their own media releases throughout their communities.

Revisions for this submission of the information collection request include two new opportunities for hospitals to earn points: a point is awarded for each donor registration a hospital motivates and points are awarded for reaching the hospital's donor registration goal. In addition, HRSA is making various formatting changes and the point values for two activities have been increased.

**Likely Respondents:** Hospital representatives, most often the organ donation champions identified by the OPOs, can download the form from *organdonor.gov* or receive it from their OPO or DLA affiliate.

**Burden Statement:** Burden in this context means the time expended by

persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; and to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
National Hospital Organ Donation Campaign's Activity Scorecard .....	1,250	1	1,250	0.367	458.75

**Jason E. Bennett,**  
 Director, Division of the Executive Secretariat.  
 [FR Doc. 2017-00792 Filed 1-13-17; 8:45 am]  
**BILLING CODE 4165-15-P**

**DEPARTMENT OF HOMELAND SECURITY**  
**U.S. Customs and Border Protection**  
**Delay of Effective Date for the Automated Commercial Environment (ACE) Becoming the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Drawback and Duty Deferral Entry and Entry Summary Filings**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.  
**ACTION:** Delay of effective date.

**SUMMARY:** On August 30, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** announcing plans to make the Automated Commercial Environment (ACE) the sole electronic data interchange (EDI) system authorized by the Commissioner of U.S. Customs and Border Protection (CBP) for processing electronic drawback and duty deferral entry and entry summary filings. The changes announced in that notice were to have been effective on October 1, 2016. On October 3, 2016, CBP published a notice in the **Federal**

**Register** announcing that the effective date for the transition to ACE as the sole CBP-authorized EDI system for electronic drawback and duty deferral entry and entry summary filings would be delayed until further notice. On December 12, 2016, CBP published a notice in the **Federal Register** announcing that the effective date for the transition would be January 14, 2017. This notice announces that the effective date for the transition has been delayed until further notice.

**DATES:** *The effective date is delayed until further notice:* CBP will publish a subsequent notice announcing the effective date when ACE will be the sole CBP-authorized EDI system for processing electronic drawback and duty deferral entry and entry summary filings, and ACS will no longer be a CBP-authorized EDI system for purposes of processing these filings.

**FOR FURTHER INFORMATION CONTACT:** Questions related to this notice may be emailed to *ASKACE@cbp.dhs.gov* with the subject line identifier reading "ACS to ACE Drawback and Duty Deferral Entry and Entry Summary Filings transition".

**SUPPLEMENTARY INFORMATION:** On August 30, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** (81 FR 59644) announcing plans to make the Automated Commercial Environment (ACE) the sole electronic data interchange (EDI) system authorized by

the Commissioner of U.S. Customs and Border Protection (CBP) for processing electronic drawback and duty deferral entry and entry summary filings, effective on October 1, 2016. The document also announced that, on October 1, 2016, the Automated Commercial System (ACS) would no longer be a CBP-authorized EDI system for purposes of processing these electronic filings. Finally, the notice announced a name change for the ACE filing code for duty deferral and the creation of a new ACE filing code for all electronic drawback filings, replacing the six distinct drawback codes previously filed in ACS. On October 3, 2016, CBP published a notice in the **Federal Register** (81 FR 68023) announcing that the effective date for these changes would be delayed until further notice. Thereafter, on December 12, 2016, CBP published a notice in the **Federal Register** (81 FR 89486) announcing that the new effective date for the transition would be January 14, 2017.

The effective date for the all that was announced in the August 30, 2016 **Federal Register** notice, including the transition to ACE as the sole CBP-authorized EDI system for electronic drawback and duty deferral entry and entry summary filings, is delayed until further notice. CBP will publish a subsequent notice announcing the effective date.

Dated: January 11, 2017.

**Brenda B. Smith,**

*Executive Assistant Commissioner, Office of Trade.*

[FR Doc. 2017-00852 Filed 1-13-17; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Delayed Effective Date for Modifications of the National Customs Automation Program Tests Regarding Reconciliation, Post-Summary Corrections, and Periodic Monthly Statements

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Delay of effective date.

**SUMMARY:** This notice announces that the effective date for the modifications to the National Customs Automation Program (NCAP) tests regarding Reconciliation, Post-Summary Corrections, and Periodic Monthly Statements is delayed until further notice. On December 12, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** announcing modifications to the National Customs Automation Program (NCAP) test regarding reconciliation, and the transition of the test from the Automated Commercial System (ACS) to the Automated Commercial Environment (ACE). The modifications made by this notice were to be effective on January 14, 2017. On December 12, 2016, U.S. Customs and Border Protection (CBP) published in the **Federal Register** a document announcing CBP's plans to modify and clarify the National Customs Automation Program (NCAP) test regarding Post-Summary Correction (PSC) claims to entry summaries that are filed in the Automated Commercial Environment (ACE), as well as the Periodic Monthly Statement (PMS) test. The notice liberalized and eliminated some requirements needed for the filing of PSCs; however, it also placed burdens on the importer in the form of a restriction and a prohibition. Subsequently, CBP published a notice in the **Federal Register** on January 9, 2017, to remove the restriction imposed on all PSC filings to make payments within three business days of submitting the PSC, with the exception of entry type 03 filings, and to remove the prohibition of filing additional PSCs until additional duties, fees and taxes

are deposited. The changes to the PSC and PMS tests were to have been effective January 14, 2017. This notice announces that the effective date for the modifications to these NCAP tests has been delayed until further notice.

**DATES:** The effective date for the modifications to the reconciliation, PSC, and PMS NCAP tests is delayed until further notice.

**ADDRESSES:** Comments concerning the reconciliation test program may be submitted any time during the test via email, with a subject line identifier reading, "Comment on Reconciliation test", to *OFO-RECONFOLDER@cbp.dhs.gov*.

Comments concerning the PSC and PMS test programs may be submitted via email to Monica Crockett at *ESARinfoinbox@dhs.gov* with a subject line identifier reading, "Post-Summary Corrections and Periodic Monthly Statements."

#### FOR FURTHER INFORMATION CONTACT:

**Reconciliation:** Acenitha Kennedy, Entry Summary and Revenue Branch, Trade Policy and Programs, Office of Trade at (202) 863-6064 or *ACENITHA.KENNEDY@CBP.DHS.GOV*.

**PSC and PMS:** For policy-related questions, contact Randy Mitchell, Director, Commercial Operations, Trade Policy and Programs, Office of Trade, at *Randy.Mitchell@cbp.dhs.gov*. For technical questions related to ABI transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Representative Branch at (703) 650-3500.

#### SUPPLEMENTARY INFORMATION:

##### Background

##### I. Reconciliation Test

On December 12, 2016, U.S. Customs and Border Protection (CBP) published a notice entitled "Modification of the National Customs Automation Program Test Regarding Reconciliation and Transition of the Test from the Automated Commercial System to the Automated Commercial Environment" in the **Federal Register** (81 FR 89486), with an effective date of January 14, 2017. This notice announced modifications to the National Customs Automation Program (NCAP) test regarding reconciliation, and the transition of the test from the Automated Commercial System (ACS) to the Automated Commercial Environment (ACE). The modifications eliminated several requirements for participation in the test, imposed new data requirements, and established the

requirement that reconciliation entries be filed in ACE regardless of whether the underlying entry was filed in ACS or ACE.

CBP has assessed stakeholder readiness for the mandatory transition of post-release capabilities in ACE, including the modifications to the reconciliation test and the transition of reconciliation filings from ACS to ACE. This notice announces that the effective date for the modifications to the reconciliation test, and for mandatory filing of reconciliation entries in ACE has been delayed until further notice.

##### II. Post-Summary Correction and Periodic Monthly Statement Tests

On December 12, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** (81 FR 89482) announcing plans to modify and clarify, effective January 14, 2017, the National Customs Automation Program (NCAP) test regarding Post-Summary Correction (PSC) claims, and the Periodic Monthly Statement (PMS) test. The modifications made by the notice eliminated or liberalized certain requirements for the filing of a PSC, making it easier for importers to file a PSC for additional entry types, and allowed filers additional time to make a deposit for duties, fees and taxes owed. With regard to the PMS test program, the notice announced the time at which CBP considers a PMS as paid when filers use the Automated Clearing House (ACH) debit process.

Subsequently, CBP decided not to implement two of the changes announced in the December 12, 2016 notice. In a notice published in the **Federal Register** (82 FR 2385) on January 9, 2017, CBP removed the requirement that additional duties, fees and taxes be submitted within three business days of filing a PSC, and limited the restriction of submitting payment to PSC filings declaring an increase of liability for antidumping/countervailing duties and associated fees and taxes. The notice also removed the prohibition of filing additional PSCs until the duties, fees and taxes are deposited. Like the changes made in the December 12, 2016 notice, these changes were to become effective on January 14, 2017. This notice announces that the effective date for the modifications to the PSC and PMS tests has been delayed until further notice.

Dated: January 11, 2017.

**Brenda B. Smith,**

*Executive Assistant Commissioner, Office of Trade.*

[FR Doc. 2017-00837 Filed 1-13-17; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2016–0089]

### National Infrastructure Advisory Council

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Committee management; notice of an Open Federal Advisory Committee meeting.

**SUMMARY:** The National Infrastructure Advisory Council (NIAC) will meet Thursday, February 16, 2017, at 1331 F Street NW., Suite 1000, Washington, DC 20004. This meeting will be open to the public.

**DATES:** The NIAC will meet on February 16, 2017. The meeting will be held from 1:30 p.m.–4:30 p.m. EST. The meeting may close early if the committee has completed its business. For additional information, please consult the NIAC Web site, [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC), or contact the NIAC Secretariat by phone at (703) 235–2888 or by email at [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov).

**ADDRESSES:** 1331 F Street NW., Suite 1000, Washington, DC 20004. Members of the public will register at the registration table prior to entering the meeting room. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the “Summary” section below. Comments must be submitted in writing no later than 12:00 p.m. on February 13, 2017, in order to be considered by the Council in its meeting. The comments must be identified by “DHS–2016–0089,” and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting written comments.
- *Email:* [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov). Include the docket number (DHS–2016–0089) in the subject line of the message.
- *Fax:* (703)235–9707.
- *Mail:* Ginger Norris, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0612, Washington, DC 20598–0607.

*Instructions:* All written submissions received must include the words “Department of Homeland Security”

and the docket number for this action. Written comments received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

*Docket:* For access to the docket or to read background documents or comments received by the NIAC, go to [www.regulations.gov](http://www.regulations.gov). Enter “NIAC” in the search line and the Web site will list all relevant documents for your review.

Members of the public will have an opportunity to provide oral comments on the topics on the meeting agenda below, and on any previous studies issued by the NIAC. We request that comments be limited to the issues and studies listed in the meeting agenda and previous NIAC studies. All previous NIAC studies can be located at [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC). Public comments may be submitted in writing or presented in person for the Council to consider. Comments received by Ginger Norris on or after 1:00 p.m. on February 16, 2017 will still be accepted and reviewed by the Members, but not necessarily at the time of the meeting. In-person presentations will be limited to three minutes per speaker, with no more than 15 minutes for all speakers. Parties interested in making in-person comments should register on the Public Comment Registration list available at the entrance to the meeting location prior to the beginning of the meeting.

**FOR FURTHER INFORMATION CONTACT:** Ginger Norris, Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, NIAC, Designated Federal Officer, 245 Murray Lane SW., Mail Stop 0607, Washington, DC 20598–0607, telephone 202–441–5885.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. appendix. The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation’s critical infrastructure sectors. The NIAC will meet to discuss issues relevant to critical infrastructure security and resilience, as directed by the President.

The meeting will commence at 1:00 p.m. EST. At this meeting, the Council will discuss its newest tasking and receive briefings. All presentations will be posted prior to the meeting on the Council’s public Web page—[www.dhs.gov/NIAC](http://www.dhs.gov/NIAC).

### Public Meeting Agenda

- I. Opening of Meeting
- II. Roll Call of Members
- III. Opening Remarks and Introductions

- IV. Approval of SEP 2016 Meeting Minutes
- V. Presentations on Future Focus Study
- VI. Public Comment
- VII. Discussion of New NIAC Business
- VIII. Closing Remarks
- IX. Adjournment

Dated: January 4, 2017.

**Ginger Norris,**

*Designated Federal Officer for the NIAC.*

[FR Doc. 2017–00789 Filed 1–13–17; 8:45 am]

**BILLING CODE 9110–9–P**

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[DHS Docket No. DHS–2017–0004]

### Eliminating Exception To Expedited Removal Authority for Cuban Nationals Encountered in the United States or Arriving by Sea

**AGENCY:** Office of the Secretary, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice concerns the authority of the Department of Homeland Security (DHS or the Department) to place certain designated categories of aliens in expedited removal proceedings. On November 13, 2002, the former Immigration and Naturalization Service (INS) of the Department of Justice issued a notice designating certain aliens who arrive by sea, either by boat or other means, as eligible for placement in expedited removal proceedings, with an exception for Cuban citizens or nationals (hereinafter “Cuban nationals”). On August 11, 2004, DHS issued a notice designating certain aliens in the United States as eligible for placement in expedited removal proceedings, also with an exception for Cuban nationals. In light of recent changes in the relationship between the United States and Cuba, the Department has determined that the exceptions for Cuban nationals, contained in the designations of November 13, 2002 and August 11, 2004, are no longer warranted and are thus hereby eliminated. The rest of the November 13, 2002 and August 11, 2004 designations, including any implementing policies, are unaffected by this notice and remain unchanged.

**DATE:** This notice is effective on January 13, 2017. Interested persons are invited to submit written comments on this notice on or before March 20, 2017.

**ADDRESSES:** You may submit comments, identified by DHS Docket Number DHS–2017–0004, by any one of the following methods:



• *Federal e-Rulemaking Portal* [www.regulations.gov](http://www.regulations.gov). Follow the Web site instructions for submitting comments.

• *Mail or Hand Delivery/Courier*: Please submit all written comments (including and CD-ROM submissions) to Amanda Baran, Principal Director for Immigration Policy, DHS, 245 Murray Lane SW., Mail Stop 0445, Washington, DC 20528.

Please submit your comments by only one method. Comments received by means other than those listed above or received after the comment period has closed will not be reviewed. All comments received will be posted without change on <http://www.regulations.gov>. The <http://www.regulations.gov> Web site is the Federal e-rulemaking portal and comments posted there are available and accessible to the public. Commenters should not include personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses in their comments as such information will become viewable by the public on the <http://www.regulations.gov> Web site. It is the commenter's responsibility to safeguard his or her information. Comments submitted through <http://www.regulations.gov> will not include the commenter's email address unless the commenter chooses to include that information as part of his or her comment.

Postal delivery in Washington, DC, may be delayed due to security concerns. Therefore, DHS encourages the public to submit comments through the <http://www.regulations.gov> Web site.

*Docket*: For access to the docket to read background documents or comments received, go to the Federal eRulemaking portal at <http://www.regulations.gov>. If you need assistance to review the comments, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section below.

**FOR FURTHER INFORMATION CONTACT:** Amanda Baran, Principal Director for Immigration Policy, 202-282-8805, [Amanda.baran@hq.dhs.gov](mailto:Amanda.baran@hq.dhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 302 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104-208, Div. C, 110 Stat. 3009-546, amended section 235(b) of the Immigration and Nationality Act ("Act"), 8 U.S.C. 1225(b), to authorize the Attorney General (now the Secretary of Homeland Security as designated under the Homeland Security Act of 2002) to

remove, without a hearing before an immigration judge, aliens arriving in the United States and certain other applicants for admission who are inadmissible under sections 212(a)(6)(C) or 212(a)(7) of the Act, 8 U.S.C. 1182(a)(6)(C) and 1182(a)(7), for lack of valid documents necessary for admission or entry or for procuring or seeking to procure a visa, other immigration-related documentation, admission to the United States, or other immigration benefit by fraud or willful misrepresentation of a material fact.

Expedited removal proceedings under section 235(b) of the Act, 8 U.S.C. 1225(b), may be applied to two categories of aliens. First, expedited removal proceedings may be used for aliens who are "arriving in the United States." Section 235(b)(1)(A)(i) of the Act, 8 U.S.C. 1225(b)(1)(A)(i). Second, the Secretary, in his or her sole and unreviewable discretion, may designate certain other aliens to whom the expedited removal provisions may be applied. Section 235(b)(1)(A)(iii) of the Act, 8 U.S.C. 1225(b)(1)(A)(iii); see 8 CFR 235.3(b)(1)(ii). Specifically, with limited exception, the Act authorizes the Secretary to apply (by designation) expedited removal proceedings to all or any subset of aliens who (1) have not been admitted or paroled following inspection by an immigration officer at a designated port-of-entry, and (2) have not established to the satisfaction of the immigration officer that they have been physically present in the United States continuously for the two-year period immediately prior to the date of determination of inadmissibility. Section 235(b)(1)(A)(iii)(I)-(II), 8 U.S.C. 1225(b)(1)(A)(iii)(I)-(II). The Secretary may modify such designations at any time. *Id.*

On November 13, 2002, the former INS issued a **Federal Register** notice announcing that it was exercising its authority under section 235(b)(1)(A)(iii) of the Act, 8 U.S.C. 1225(b)(1)(A)(iii), to designate additional aliens who may be placed in expedited removal proceedings. 67 FR 68924. Specifically, that notice designated the following class of aliens who may be placed in expedited removal proceedings: "all aliens who arrive in the United States by sea, either by boat or other means, who are not admitted or paroled, and who have not been physically present in the United States continuously for the two-year period prior to a determination of inadmissibility." *Id.* The INS noted at the time that "[p]lacing these individuals in expedited removal proceedings and maintaining detention for the duration of all immigration proceedings, with limited exceptions,

will ensure prompt immigration determinations and ensure removal from the country of those not granted relief in those cases, while at the same time protecting the rights of the individuals affected." *Id.* The INS also stated that "exercising its authority to detain this class of aliens . . . will assist in deterring surges in illegal migration by sea, including potential mass migration, and preventing loss of life." *Id.* The INS further noted that preventing illegal migration by sea also protects national security, as "[a] surge in illegal migration by sea threatens [that] security by diverting valuable United States Coast Guard and other resources from counter-terrorism and homeland security responsibilities." *Id.*

The November 13, 2002 notice, however, contained an exception for Cuban nationals who are otherwise described in the designated class, stating that expedited removal proceedings would not be initiated against such Cuban nationals who arrive by sea. *Id.* The INS based this exception on "longstanding U.S. policy to treat Cubans differently from other aliens," citing the Cuban Adjustment Act, Public Law 89-732 (1966) (8 U.S.C. 1255 note), as an example of such treatment. *Id.* The notice also cited section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F), which at the time statutorily exempted Cuban nationals who arrived by aircraft at a U.S. port of entry from being placed into expedited removal proceedings because of the lack of diplomatic relations between the United States and Cuba. That section expressly provides that expedited removal "shall not apply to an alien who is a native or citizen of a country in the Western Hemisphere with whose government the United States does not have full diplomatic relations and who arrives by aircraft at a port of entry." Section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F).

On August 11, 2004, DHS issued a similar **Federal Register** notice announcing that it was exercising its authority under section 235(b)(1)(A)(iii), 8 U.S.C. 1225(b)(1)(A)(iii), to designate an additional class of aliens who may be placed in expedited removal proceedings. 69 FR 48877. That notice authorized the Department to place in expedited removal proceedings any or all members of the following class of aliens: "Aliens determined to be inadmissible under sections 212(a)(6)(C) or (7) of the Immigration and Nationality Act who are present in the U.S. without having been admitted or paroled following inspection by an immigration officer at a designated port of entry, who are encountered by an immigration officer within 100 air miles

of the U.S. international land border, and who have not established to the satisfaction of an immigration officer that they have been physically present in the U.S. continuously for the fourteen-day (14-day) period immediately prior to the date of encounter.” *Id.* DHS noted at the time that “exercising its statutory authority to place these individuals in expedited removal proceedings will enhance national security and public safety by facilitating prompt immigration determinations, enabling DHS to deal more effectively with the large volume of persons seeking illegal entry, and ensure removal from the country of those not granted relief, while at the same time protecting the rights of the individuals affected.” *Id.*

Like the November 13, 2002 notice, the August 11, 2004 notice contained an exception for Cuban nationals who are otherwise described in the designated class and stated that expedited removal proceedings would not be initiated against such nationals encountered in the United States. *Id.* The notice similarly based this exception on that fact that “removals to Cuba [could not] presently be assured and for other U.S. policy reasons,” *id.*, citing section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F), as well.

Since those notices were issued, significant changes in the relationship between the United States and Cuba have occurred. In December 2014, President Obama announced a historic opening between the United States and Cuba, as well as an approach for reestablishing diplomatic relations and adjusting regulations to facilitate greater travel, commerce, people-to-people ties, and the free flow of information to, from, and within Cuba. On July 20, 2015, the United States and Cuba formally reestablished full diplomatic relations and opened embassies in each other’s countries. In the time following the reestablishment of full diplomatic relations, the United States and Cuba have taken concrete steps towards enhancing security, building bridges between our peoples, and promoting economic prosperity for citizens of both countries. And recent migration discussions have yielded important changes that will dramatically affect travel and migration between our two countries. Among other things, Cuba has agreed to accept and facilitate the repatriation of its nationals who are ordered removed from the United States. This arrangement and other changes remain the focus of ongoing diplomatic discussions between the two countries.

DHS also has recently seen a significant increase in attempts by Cuban nationals to illegally enter the United States. Many of those Cuban nationals have taken a dangerous journey through Central America and Mexico; others have taken to the high seas in the dangerous attempt to cross the Straits of Florida. DHS believes this increase in attempted migration has been driven in part by the perception that there is a limited window before the United States will eliminate favorable immigration policies for Cuban nationals.

The application of the expedited removal authorities to Cuban nationals must reflect these new realities. First, the Department notes that the statutory provision categorically barring the use of expedited removal for certain aliens who arrive by aircraft at a U.S. port of entry no longer applies to Cuban nationals, as the United States and Cuba have reestablished full diplomatic relations. *See* section 235(b)(1)(F) of the Act, 8 U.S.C. 1225(b)(1)(F). In fact, DHS and DOJ are promulgating rules in this issue of the **Federal Register**, amending 8 CFR 235.3(b)(1)(i) and 1235.3(b)(1)(i) to strike the regulatory exception for Cuban nationals arriving by aircraft at a U.S. port of entry. Second, the improved relationship between the United States and Cuba, along with Cuba’s agreement to accept the repatriation of its nationals, has eroded certain U.S. policy justifications for the exception. Finally, a categorical exception severely impairs the Government’s ability to remove unauthorized aliens encountered within the United States. For these reasons, DHS has determined, in consultation with the Department of State, that a categorical exception from expedited removal for Cuban nationals is no longer in the interests of the United States.

Accordingly, this notice eliminates the categorical exceptions for Cuban nationals, with respect to both the November 13, 2002 and August 11, 2004 notices, on a prospective basis, beginning on January 13, 2017, *see* 8 CFR 235.3(b)(1)(ii) (designation may be effective as early as the date of issuance). As a result, Cuban nationals encountered on or after January 13, 2017 are included in the classes of aliens subject to expedited removal as designated in the November 13, 2002 and August 11, 2004 notices. DHS is not changing any other aspects of those designations and, apart from the modification described above, will continue exercising its expedited removal authority as indicated in the November 13, 2002 and August 11, 2004 notices.

As it did for the November 13, 2002 and August 11, 2004 notices, and consistent with implementing regulations at 8 CFR 235.3(b)(1)(ii), the Department has determined that good cause exists to exempt this notice from the notice-and-comment and 30-day delayed effective date requirements under the Administrative Procedure Act (APA). *See* 5 U.S.C. 553(b)(3)(B) and (d)(3). Delaying the implementation of this notice to allow public notice and comment would be impracticable and contrary to the public interest. Congress explicitly authorized the Secretary to designate categories of aliens to whom expedited removal proceedings may be applied, and made clear that “[s]uch designation shall be in the sole and unreviewable discretion of the Secretary and may be modified at any time.” Section 235(b)(1)(A)(iii)(I) of the Act, 8 U.S.C. 1225(b)(1)(A)(iii)(I).

Moreover, as with the August 11, 2004 notice, the designation in this notice is necessary to remove quickly from the United States aliens who are encountered shortly after illegally entering across U.S. land borders. The ability to detain such aliens while admissibility and identity are determined and protection claims are adjudicated, as well as to quickly remove those without protection claims or claims to lawful status, is a necessity for national security and public safety.

DHS has determined that pre-promulgation notice and comment would undermine these interests, while endangering human life and having a potential destabilizing effect in the region. Among other things, such opportunity for notice and comment could result in a surge in migration of Cuban nationals seeking to travel to and enter the United States prior to the effectuation of the changes announced in this notice. Such a surge would threaten national security and public safety by diverting valuable Government resources from counterterrorism and homeland security responsibilities. *See Matter of D-J*, I. & N. Dec. 572, 579 (A.G. 2003). A surge could also have a destabilizing effect on the region, thus weakening the security of the United States and threatening its international relations. Additionally, a surge in migration over land or sea could result in significant loss of human life. For the foregoing reasons, the Department has determined that public notice and comment prior to promulgation of this notice would be impracticable and contrary to the public interest.

In addition, the change implemented by this notice is part of a major foreign policy initiative announced by the President, and is central to ongoing

diplomatic discussions between the United States and Cuba with respect to travel and migration between the two countries. DHS, in consultation with the Department of State, has determined that eliminating the exception from expedited removal proceedings for Cuban nationals involves a foreign affairs function of the United States, 5 U.S.C. 553(a)(1), and that this notice is exempt from APA procedural requirements on that basis.

Finally, and for the same reasons described above, DHS finds that delay caused by publication would adversely affect the interests of the United States and the effective enforcement of the immigration laws, and therefore invokes 8 CFR 235.3(b)(1)(ii) to make this designation effective immediately upon placement on public inspection.

Although advance notice and comment procedures are not in the interests of the United States with respect to this notice, DHS is interested in receiving comments from the public on the elimination of the categorical exception for Cuban nationals. DHS believes that by maintaining a dialogue with interested parties, DHS may be better positioned to ensure that the program is even more effective in combating and deterring illegal entry, while at the same time protecting the rights of the individuals affected.

#### Notice of Designation of Aliens Subject to Expedited Removal Proceedings

Pursuant to section 235(b)(1)(A)(iii) of the Immigration and Nationality Act (8 U.S.C. 1225(b)(1)(A)(iii)) and 8 CFR 235.3(b)(1)(ii), I order as follows:

(1) With respect to the above-referenced Designation of November 13, 2002, 67 FR 68924, I hereby rescind the provision at numbered paragraph (5), specifying that “[e]xpedited removal proceedings will not be initiated against Cuban citizens or nationals who arrive by sea,” and other language of the Designation referencing or relating to that exception for Cuban citizens or nationals.

(2) With respect to the above-referenced Designation of August 11, 2004, 69 FR 48877, I hereby rescind the provision at numbered paragraph (6), specifying that “[t]he expedited removal proceedings contemplated by this notice will not be initiated against Cuban citizens or nationals,” and other language of the Designation referencing or relating to that exception for Cuban citizens or nationals.

Signed: at Washington, DC this 11th of January, 2017.

**Jeh Charles Johnson,**

*Secretary of Homeland Security.*

[FR Doc. 2017-00914 Filed 1-13-17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[CIS No. 2593-16; DHS Docket No. USCIS-2015-USCIS-2013-0006]

RIN 1615-ZB62

#### Extension of the Designation of Somalia for Temporary Protected Status

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** The Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of Somalia for Temporary Protected Status (TPS) for a period of 18 months, effective March 18, 2017 through September 17, 2018. This extension allows eligible Somali nationals (and aliens having no nationality who last habitually resided in Somalia) to retain TPS through September 17, 2018, so long as they otherwise continue to meet the eligibility requirements for TPS. The Secretary has determined that an extension is warranted because conditions in Somalia supporting its designation for TPS continue to be met. Through this Notice, DHS also sets forth procedures necessary for nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia) to re-register for TPS and to apply for renewal of their Employment Authorization Documents (EAD) with U.S. Citizenship and Immigration Services (USCIS).

**DATES:** The 18-month extension of the TPS designation of Somalia is effective as of March 18, 2017, and will remain in effect through September 17, 2018. The 60-day re-registration period runs from January 17, 2017 through March 20, 2017. Note: It is important for registrants to timely re-register during this 60-day period and not to wait until their EADs expire.

#### FOR FURTHER INFORMATION CONTACT:

• For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS

Web page at <http://www.uscis.gov/tps>. You can find specific information about the extension of Somalia’s designation for TPS by selecting “Somalia” from the menu on the left side of the TPS Web page.

• You can also contact Guillermo Roman-Riefkohl, TPS Program Manager, Waivers and Temporary Services Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529-2060; or by phone at 202-272-1533 (this is not a toll-free number).

**Note:** The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquiries.

• Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833). Service is available in English and Spanish.

• Further information will also be available at local USCIS offices upon publication of this Notice.

#### SUPPLEMENTARY INFORMATION:

##### Table of Abbreviations

BIA—Board of Immigration Appeals  
 DHS—Department of Homeland Security  
 EAD—Employment Authorization Document  
 FNC—Final Nonconfirmation  
 Government—U.S. Government  
 JJ—Immigration Judge  
 INA—Immigration and Nationality Act  
 OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices  
 SAVE—USCIS Systematic Alien Verification for Entitlements Program  
 Secretary—Secretary of Homeland Security  
 TNC—Tentative Nonconfirmation  
 TPS—Temporary Protected Status  
 TTY—Text Telephone  
 USCIS—U.S. Citizenship and Immigration Services

#### What is Temporary Protected Status (TPS)?

• TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the Immigration and Nationality Act (INA), or to eligible aliens without nationality who last habitually resided in the designated country.

• During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and obtain EADs, so long as they continue to meet the requirements of TPS.

- TPS beneficiaries may be granted travel authorization as a matter of discretion.
- The granting of TPS does not result in or lead to lawful permanent resident status.
- When the Secretary terminates a country's TPS designation through a separate **Federal Register** notice, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

#### **When and why was Somalia designated for TPS?**

On September 16, 1991, the Attorney General designated Somalia for TPS based on extraordinary and temporary conditions. *See* 56 FR 46804 (Sept. 16, 1991). The initial designation was extended nine times based on determinations that the conditions warranting the designation continued to be met. On September 4, 2001, the Attorney General extended Somalia's TPS designation for a tenth time and redesignated Somalia for TPS. *See* 66 FR 46288 (Sept. 4, 2001). Under the 2001 redesignation, the Attorney General revised the date from which applicants had to show they had been "continuously residing" in and "continuously physically present" in the United States to September 4, 2001. Somalia's TPS designation was subsequently extended nine additional times, including on May 1, 2012, when the Secretary both extended and redesignated Somalia for TPS and added ongoing armed conflict as an additional basis for Somalia's TPS designation. Under the 2012 redesignation, the Secretary revised the "continuous residence" date to May 1, 2012, and the "continuous physical presence" date to September 18, 2012. *See* 77 FR 25723 (May 1, 2012). This announcement is the third extension of the Somalia designation for TPS since the 2012 extension and redesignation.

#### **What is the effect of this extension of Somalia's designation for TPS?**

This extension of Somalia's designation for TPS allows eligible Somali nationals (and aliens having no nationality who last habitually resided in Somalia) who currently hold TPS to retain it through September 17, 2018, so long as they otherwise continue to meet the eligibility requirements for TPS. Current beneficiaries who wish to maintain their TPS should file a re-registration application with USCIS.

They may also apply for renewal of their EADs.

Re-registration is limited to persons who have previously registered for TPS under the designation of Somalia and whose applications have been granted. Certain nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia) who have not previously applied for TPS may be eligible to apply under the late initial registration provisions, if they meet: (1) At least one of the late initial filing criteria; and (2) all TPS eligibility criteria (including continuous residence in the United States since May 1, 2012, and continuous physical presence in the United States since September 18, 2012).

For individuals who have already been granted TPS under Somalia's designation, the 60-day re-registration period runs from January 17, 2017 through March 20, 2017. USCIS will issue new EADs with a September 17, 2018 expiration date to eligible Somalia TPS beneficiaries who timely re-register and apply for EADs under this extension. Given the timeframes involved with processing TPS re-registration applications, DHS recognizes that not all re-registrants will receive new EADs before their current EADs expire on March 17, 2017. Accordingly, through this Notice, DHS automatically extends the validity of EADs issued under the TPS designation of Somalia for 6 months, through September 17, 2017, and explains how TPS beneficiaries and their employers may determine which EADs are automatically extended and their impact on the Employment Eligibility Verification (Form I-9) and E-Verify processes.

#### **What authority does the Secretary have to extend the designation of Somalia for TPS?**

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate U.S. Government (Government) agencies, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.<sup>1</sup> Following the designation of a foreign state for TPS, the Secretary may then grant TPS to eligible nationals of that foreign state (or eligible aliens having no

nationality who last habitually resided in that state). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A). Applicants must demonstrate that they satisfy all eligibility criteria, including that they have been "continuously physically present" in the United States since the effective date of the designation, which is either the date of the **Federal Register** notice announcing the designation or such later date as the Secretary may determine, and that they have "continuously resided" in the United States since such date as the Secretary may designate. *See* INA sections 244(a)(1)(A), (b)(2)(A), (c)(1)(A)(i-ii); 8 U.S.C. 1254a(a)(1)(A), (b)(2)(A), (c)(1)(A)(i-ii).

#### **Why is the Secretary extending the TPS designation for Somalia through September 17, 2018?**

DHS, in consultation with the Department of State, has conducted a thorough review of conditions in Somalia. Based on this review, the Secretary has determined that an 18-month extension of Somalia's designation for TPS is warranted because the conditions that supported its 2012 redesignation—(1) ongoing armed conflict and (2) extraordinary and temporary conditions that prevent Somali nationals from returning to Somalia in safety—continue to exist. The Secretary has further determined that permitting eligible Somali nationals to remain temporarily in the United States is not contrary to the national interest of the United States.

The security situation in Somalia remains fragile and volatile, with much of Somalia in a state of ongoing armed conflict between government forces, clan militia, African Union troops, and al-Shabaab. Al-Shabaab controls large swaths of territory in southern Somalia and conducts frequent asymmetric attacks on military and civilian targets in government-controlled areas. Additionally, some parts of the country not under al-Shabaab control experience high levels of insecurity due to inter- and intra-clan conflict. Members of minority clans are systematically marginalized, abused, and sometimes killed by members of larger clans. Minority clan members have also been largely displaced from their original territories in Somalia, and members of those clans who return to Somalia may find themselves in displaced persons camps. Individuals living in informal camps for displaced persons have been subjected to serious abuses, including rape, physical attacks, restricted access to humanitarian assistance, and clan-based discrimination.

<sup>1</sup> As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107-296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS "shall be deemed to refer to the Secretary" of Homeland Security. *See* 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

Somalia continues to experience a complex protracted emergency that is one of the worst humanitarian crises in the world. Approximately 5 million people (over 40 percent of the total population of around 11 million) are in need of humanitarian assistance, and there are an estimated 1.1 million internally displaced persons. Malnutrition rates in Somalia are among the highest in the world, with an estimated one million people experiencing acute food insecurity. The 2015–2016 El Niño phenomenon has intensified extensive flooding and severe drought, with the drought conditions contributing to deteriorating food security in northern areas of the country. Non-permanent water sources, such as dams and streams are drying up, driving up the price of water. Vulnerable households are forced to consume unsafe water because they are unable to pay the high cost.

Approximately 3.2 million people in Somalia lack sufficient access to emergency health care services, and about 1.9 million people are at risk of dying of preventable diseases due to lack of access to primary health care services. The maternal mortality rate in Somalia is among the highest in the world. Due to the drought, health facilities have seen an increase in waterborne communicable diseases, as the only available remaining water sources are shared by humans and livestock. Health facilities have also recorded an increased incidence of diseases associated with a lack of water and poor hygiene, namely skin diseases, respiratory infections, and febrile illnesses.

Based upon DHS's review of conditions in Somalia and after consultation with appropriate Government agencies, the Secretary has determined that:

- The conditions that prompted the May 1, 2012 redesignation of Somalia for TPS continue to be met. *See* INA section 244(b)(1)(A) and (C), (b)(3)(A) and (C); 8 U.S.C. 1254a(b)(1)(A) and (C), (b)(3)(A) and (C).
- There continues to be an ongoing armed conflict in Somalia and, due to such conflict, requiring the return of Somali nationals would pose a serious threat to their safety. *See* INA section 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A).
- There continue to be extraordinary and temporary conditions in Somalia that prevent Somali nationals from returning to Somalia in safety. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).
- It is not contrary to the national interest of the United States to permit Somalis (and persons who have no

nationality who last habitually resided in Somalia) who meet the eligibility requirements of TPS to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).

- The designation of Somalia for TPS should be extended for an additional 18-month period from March 18, 2017 through September 17, 2018. *See* INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).

Based on data from the last re-registration period, DHS expects approximately 250 beneficiaries under Somalia's TPS designation to file for re-registration under the extension.

#### **Notice of Extension of the TPS Designation of Somalia**

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate Government agencies, that the conditions supporting the most recent designation of Somalia for Temporary Protected Status (TPS) on May 1, 2012 continue to be met. *See* INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). On the basis of this determination, I am extending the designation of Somalia for TPS for 18 months from March 18, 2017 through September 17, 2018. *See* INA section 244(b)(1)(A) and (C), (b)(2); 8 U.S.C. 1254a(b)(1)(A) and (C), (b)(2).

**Jeh Charles Johnson,**  
*Secretary.*

#### **I am currently a Somalia TPS beneficiary. What should I do?**

If you are a current TPS beneficiary, then you need to file a re-registration application under the extension if you wish to maintain TPS benefits through September 17, 2018. You must use the Application for Temporary Protected Status (Form I-821) to re-register for TPS. The 60-day open re-registration period will run from January 17, 2017 through March 20, 2017.

#### **Required Application Forms and Application Fees To Register or Re-Register for TPS**

To register or re-register for TPS based on the designation of Somalia, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I-821).
  - If you are filing an application for late initial registration, you must pay the fee for the Application for Temporary Protected Status (Form I-821). *See* 8 CFR 244.2(f)(2) and 244.6 and information on late initial filing on

the USCIS TPS Web page at <http://www.uscis.gov/tps>.

- If you are filing an application for re-registration, you do not need to pay the fee for the Application for Temporary Protected Status (Form I-821). *See* 8 CFR 244.17. and
  2. Application for Employment Authorization (Form I-765).
    - If you are applying for late initial registration and want an EAD, you must pay the fee for the Application for Employment Authorization (Form I-765) only if you are age 14 through 65. No fee for the Application for Employment Authorization (Form I-765) is required if you are under the age of 14 or are 66 and older and applying for late initial registration.
    - If you are applying for re-registration, you must pay the fee for the Application for Employment Authorization (Form I-765) only if you want an EAD, regardless of age.
    - You do not pay the fee for the Application for Employment Authorization (Form I-765) if you are not requesting an EAD, regardless of whether you are applying for late initial registration or re-registration.

You must submit both completed application forms together. If you are unable to pay for the Application for Employment Authorization (Form I-765) and/or biometric services fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I-912) or submit a personal letter requesting a fee waiver, and provide satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. Fees for the Application for Temporary Protected Status (Form I-821), the Application for Employment Authorization (Form I-765), and biometric services are also described in 8 CFR 103.7(b)(1)(i).

#### **Biometric Services Fee**

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I-912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at <http://www.uscis.gov>. If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

**Re-Filing a Re-Registration TPS Application After Receiving a Denial of a Fee Waiver Request**

USCIS urges all re-registering applicants to file as soon as possible within the 60-day re-registration period so that USCIS can process the applications and issue EADs promptly. Filing early will also allow those applicants who may receive denials of their fee waiver requests to have time to re-file their applications before the re-registration deadline. If, however, an applicant receives a denial of his or her fee waiver request and is unable to re-file by the re-registration deadline, the applicant may still re-file his or her

application. This situation will be reviewed to determine whether the applicant has established good cause for late re-registration. However, applicants are urged to re-file within 45 days of the date on their USCIS fee waiver denial notice, if at all possible. See INA section 244(c)(3)(C); 8 U.S.C. 1254a(c)(3)(C); 8 CFR 244.17(c). For more information on good cause for late re-registration, visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. Note: As previously stated, although a re-registering TPS beneficiary age 14 and older must pay the biometric services fee (but not the initial TPS application fee) when filing a TPS re-registration application, the

applicant may decide to wait to request an EAD, and therefore not pay the Application for Employment Authorization (Form I-765) fee, until after USCIS has approved the individual's TPS re-registration, if he or she is eligible. If you choose to do this, you would file the Application for Temporary Protected Status (Form I-821) with the fee and the Application for Employment Authorization (Form I-765) without the fee and without requesting an EAD.

**Mailing Information**

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If you:	Then mail your application to:
Would like to send your application by U.S. Postal Service .....	USCIS Attn: TPS Somalia, P.O. Box 6943, Chicago, IL 60680-6943.
Would like to send your application by non-U.S. Postal Service courier	USCIS Attn: TPS Somalia, 131 S. Dearborn, 3rd Floor, Chicago, IL 60603-5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, please mail your application to the address in Table 1. After you submit your EAD application and receive a USCIS receipt number, please send an email to the Service Center handling your application. The email should include the receipt number and state that you submitted a request for an EAD based on an IJ/BIA grant of TPS. This will aid in the verification of your grant of TPS and processing of your EAD application, as USCIS may not have received records of your grant of TPS by either the IJ or the BIA. To obtain additional information, including the email address of the appropriate Service Center, you may go to the USCIS TPS Web page at <http://www.uscis.gov/tps>.

**E-Filing**

You cannot electronically file your application packet. Please mail your application packet to the mailing address listed in Table 1.

**Supporting Documents**

The filing instructions on the Application for Temporary Protected Status (Form I-821) list all the documents needed to establish basic eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying or registering for TPS on the USCIS Web site at [www.uscis.gov/tps](http://www.uscis.gov/tps) under "Somalia."

**Do I need to submit additional supporting documentation?**

If one or more of the questions listed in Part 4, Question 2 of the Application for Temporary Protected Status (Form I-821) applies to you, then you must submit an explanation on a separate sheet(s) of paper and/or additional documentation.

**Employment Authorization Document (EAD)**

*How can I obtain information on the status of my EAD request?*

To get case status information about your TPS application, including the status of a request for an EAD, you can check Case Status Online at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833). If your Application for Employment Authorization (Form I-765) has been pending for more than 90 days and you still need assistance, you may request an EAD inquiry appointment with USCIS by using the InfoPass system at <https://infopass.uscis.gov>. However, we strongly encourage you first to check Case Status Online or call the USCIS National Customer Service Center for assistance before making an InfoPass appointment.

*Am I eligible to receive an automatic 6-month extension of my current EAD through September 17, 2017?*

Provided that you currently have TPS under the designation of Somalia, this Notice automatically extends your EAD by 6 months if you:

- Are a national of Somalia (or an alien having no nationality who last habitually resided in Somalia);
- Have an EAD under the designation of TPS for Somalia with a marked expiration date of March 17, 2017, bearing the notation "A-12" or "C-19" on the face of the card under "Category."

Although this Notice automatically extends your EAD through September 17, 2017, you must re-register timely for TPS in accordance with the procedures described in this Notice if you would like to maintain your TPS.

*When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Form I-9, Employment Eligibility Verification?*

You can find a list of acceptable document choices on the "Lists of Acceptable Documents" for Form I-9. You can find additional detailed information on the USCIS I-9 Central Web page at <http://www.uscis.gov/I-9Central>. Employers are required to verify the identity and employment authorization of all new employees by using Form I-9. Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization) or one document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). Alternatively, you may present an acceptable receipt for List A,

List B, or List C documents as described in the Form I-9 Instructions. An EAD is an acceptable document under List A. Employers may not reject a document based on a future expiration date.

If your EAD has an expiration date of March 17, 2017, and states “A-12” or “C-19” under “Category,” it has been extended automatically for 6 months by virtue of this **Federal Register** Notice, and you may choose to present your EAD to your employer as proof of identity and employment authorization for Form I-9 through September 17, 2017 (see the subsection titled, “*How do my employer and I complete Form I-9 using an automatically extended EAD for a new job?*” for further information). To minimize confusion over this extension at the time of hire, you should explain to your employer that USCIS has automatically extended your EAD through September 17, 2017. You may also show your employer a copy of this **Federal Register** Notice confirming the automatic extension of employment authorization through September 17, 2017. As an alternative to presenting your automatically extended EAD, you may choose to present any other acceptable document from List A, a combination of one selection from List B and one selection from List C, or a valid receipt.

*What documentation may I show my employer if I am already employed but my current TPS-related EAD is set to expire?*

Even though EADs with an expiration date of March 17, 2017, that state “A-12” or “C-19” under “Category” have been automatically extended for 6 months by this **Federal Register** Notice, your employer will need to ask you about your continued employment authorization once September 17, 2017, is reached to meet its responsibilities for Form I-9 compliance. Your employer may need to reinspect your automatically extended EAD to check the expiration date and code to record the updated expiration date on your Form I-9 if he or she did not keep a copy of this EAD when you initially presented it. However, your employer does not need a new document to reverify your employment authorization until September 17, 2017, the expiration date of the automatic extension. Instead, you and your employer must make corrections to the employment authorization expiration dates in Sections 1 and 2 of Form I-9 (see the subsection titled, “*What corrections should my current employer and I make to Form I-9 if my EAD has been automatically extended?*” for further information). In addition, you may also

show this **Federal Register** Notice to your employer to explain what to do for Form I-9.

By September 17, 2017, the expiration date of the automatic extension, your employer must reverify your employment authorization. At that time, you must present any document from List A or any document from List C on Form I-9 to reverify employment authorization, or an acceptable List A or List C receipt described in the Form I-9 Instructions. Your employer should complete either Section 3 of the Form I-9 originally completed for you or, if this Section has already been completed or if the version of Form I-9 has expired (check the date in the upper right-hand corner of the form), complete Section 3 of the most current version of Form I-9. Note that employers may not specify which List A or List C document employees must present and cannot reject an acceptable receipt.

*Can my employer require that I produce any other documentation to prove my status, such as proof of my Somali citizenship?*

No. When completing Form I-9, including re-verifying employment authorization, employers must accept any documentation that appears on the Lists of Acceptable Documents and that reasonably appears to be genuine and that relates to you or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the Lists of Acceptable Documents. Therefore, employers may not request proof of Somali citizenship or proof of re-registration for TPS when completing Form I-9 for new hires, making corrections, or re-verifying the employment authorization of current employees. If presented with EADs that have been automatically extended, employers should accept such EADs as valid List A documents so long as the EADs reasonably appear to be genuine and to relate to the employee. Refer to the *Note to Employees* section of this Notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

*What happens after September 17, 2017, for purposes of employment authorization?*

After September 17, 2017, employers may no longer accept the EADs that this **Federal Register** Notice automatically extended. Before that time, however, USCIS will endeavor to issue new EADs

to eligible TPS re-registrants who request them. These new EADs will have an expiration date of September 17, 2018 and can be presented to your employer for completion of Form I-9. Alternatively, you may choose to present any other legally acceptable document or combination of documents listed on the Lists of Acceptable Documents for Form I-9.

*How do my employer and I complete Form I-9 using an automatically extended EAD for a new job?*

When using an automatically extended EAD to complete Form I-9 for a new job prior to September 17, 2017, you and your employer should do the following:

1. For Section 1, you should:
    - a. Check “An alien authorized to work;”
    - b. Enter the automatically extended EAD expiration date (September 17, 2017) in the first space; and
    - c. Enter your Alien Number (USCIS number or A-Number) in the second space (your EAD or other document from DHS will have your USCIS number or A-Number printed on it; the USCIS number is the same as your A-Number without the A prefix).
  2. For Section 2, employers should enter the:
    - a. Document title;
    - b. Issuing authority;
    - c. Document number; and
    - d. Automatically extended EAD expiration date (September 17, 2017).
- By September 17, 2017, employers must reverify the employee’s employment authorization in Section 3 of Form I-9.

*What corrections should my current employer and I make to Form I-9 if my EAD has been automatically extended?*

If you are an existing employee who presented a TPS-related EAD that was valid when you first started your job, but that EAD has now been automatically extended, your employer may need to reinspect your automatically extended EAD if your employer does not have a copy of the EAD on file, and you and your employer should correct your previously completed Form I-9 as follows:

1. For Section 1, you should:
  - a. Draw a line through the expiration date in the first space;
  - b. Write “September 17, 2017,” above the previous date;
  - c. Write “TPS Ext.” in the margin of Section 1; and
  - d. Initial and date the correction in the margin of Section 1.
2. For Section 2, employers should:
  - a. Draw a line through the expiration date written in Section 2;



b. Write "September 17, 2017," above the previous date;

c. Write "TPS Ext." in the Additional Information field in Section 2; and

d. Initial and date the correction in the Additional Information field in Section 2.

By September 17, 2017, when the automatic extension of EADs expires, employers must reverify the employee's employment authorization in Section 3.

*If I am an employer enrolled in E-Verify, what do I do when I receive a "Work Authorization Documents Expiration" alert for an automatically extended EAD?*

E-Verify automated the verification process for employees whose TPS status was automatically extended in a **Federal Register** notice. If you have an employee who is a TPS beneficiary who provided a TPS-related EAD when he or she first started working for you, you will receive a "Work Authorization Documents Expiring" case alert when the auto-extension period for this EAD is about to expire. By September 17, 2017, you must reverify employment authorization in Section 3. Employers should not use E-Verify for reverification.

#### Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888-464-4218 (TTY 877-875-6028) or email USCIS at [I-9Central@dhs.gov](mailto:I-9Central@dhs.gov). Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification (Form I-9 and E-Verify) process, employers may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Employer Hotline, at 800-255-8155 (TTY 800-237-2515), which offers language interpretation in numerous languages, or email OSC at [oscrt@usdoj.gov](mailto:oscrt@usdoj.gov).

#### Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888-897-7781 (TTY 877-875-6028) or email at [I-9Central@dhs.gov](mailto:I-9Central@dhs.gov). Calls are accepted in English and many other

languages. Employees or applicants may also call the OSC Worker Information Hotline at 800-255-7688 (TTY 800-237-2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, including information regarding discrimination related to Form I-9 and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents for Form I-9 if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Form I-9 Instructions. Employers may not require extra or additional documentation beyond what is required for Form I-9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of "Tentative Nonconfirmation" (TNC) must promptly and privately inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Form I-9 differs from Federal or state government records.

Employers may not terminate, suspend, delay training, withhold pay, lower pay, or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888-897-7781 (TTY 877-875-6028). An employee who believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker Information Hotline at 800-255-7688 (TTY 800-237-2515). Additional information about proper nondiscriminatory Form I-9 and E-Verify procedures is available on the OSC Web site at <http://www.justice.gov/crt/about/osc/> and the USCIS Web site at <http://www.dhs.gov/E-verify>.

#### Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, state, and local

government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, state, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS.

Examples are:

(1) Your unexpired EAD that has been automatically extended or your EAD that has not expired;

(2) A copy of this **Federal Register** Notice if your EAD is automatically extended under this Notice;

(3) A copy of your Application for Temporary Protected Status Notice of Action (Form I-797) for this re-registration;

(4) A copy of your past or current Application for Temporary Protected Status Notice of Action (Form I-797), if you received one from USCIS; or

(5) If there is an automatic extension of work authorization, information from the USCIS TPS Web site that provides information about the automatic extension.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to confirm the current immigration status of applicants for public benefits. In most cases, SAVE provides an automated electronic response to benefit granting agencies within seconds but occasionally verification can be delayed. You can check the status of your SAVE verification by using CaseCheck at the following link: <https://save.uscis.gov/casecheck/>, then click the "Check Your Case" button. CaseCheck is a free and fast service that lets you follow the progress of your SAVE verification using your date of birth and one immigration identifier number. If a benefit-granting agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment,

or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at <http://www.uscis.gov/save>, then by choosing “For Benefit Applicants” from the menu on the left and selecting “Questions about your Records?”

[FR Doc. 2016-31861 Filed 1-13-17; 8:45 am]

BILLING CODE 9111-97-P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5977-N-01]

### Waiver of Requirements for the State of New York: CDBG Disaster Recovery Grants for Recovery of Lower Manhattan

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public of an additional waiver applicable to the Community Development Block Grant Disaster Recovery (CDBG-DR) grants provided to the State of New York for the purpose of assisting in the recovery from the September 11, 2001, terrorist attacks on New York City. As described in the “Background” section of this notice, HUD is authorized by statute and regulations to waive statutory and regulatory requirements and specify alternative requirements for this purpose upon the request of the grantee.

**DATES:** *Effective Date:* January 23, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Stanley Gimont, Director, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 7th Street SW., Room 7286, Washington, DC 20410, telephone number 202-708-3587. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800-877-8339. Facsimile inquiries may be sent to Mr. Gimont at 202-401-2044. (Except for the “800” number, these telephone numbers are not toll-free.) Email inquiries may be sent to [disaster\\_recovery@hud.gov](mailto:disaster_recovery@hud.gov).

#### Table of Contents

- I. Background
- II. Applicable Rules, Statutes, Waivers, and Alternative Requirements
- III. Catalog of Federal Domestic Assistance
- IV. Finding of No Significant Impact

#### I. Background

Provisions of four public laws (the Appropriation Acts) govern the Community Development Block Grant

Disaster Recovery (CDBG-DR) grants covered by this Notice:

- The fifth proviso under the 2001 Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States (Pub. L. 107-38, approved September 18, 2001);
- Section 434 of title IV of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 2002 (Pub. L. 107-73, approved November 26, 2001);
- Chapter 13 of division B of the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act, 2002 (Pub. L. 107-117, approved January 10, 2002); and
- Chapter 13 of title II of the 2002 Supplemental Appropriations Act for Further Recovery from and Response to Terrorist Attacks on the United States (Pub. L. 107-206, approved August 2, 2002).

These Appropriation Acts funded three CDBG-DR grants: A single grant of \$700 million awarded to Empire State Development Corporation (ESDC); and two grants of \$2.0 billion and \$783 million, respectively, awarded to the Lower Manhattan Development Corporation (LMDC). ESDC is a political subdivision and public benefit corporation of the state of New York and LMDC is a subsidiary of ESDC.

This Notice specifies waivers and alternative requirements and modifies previous requirements applicable to LMDC’s grants under the Appropriation Acts, which are described in **Federal Register** Notices published by the Department on January 28, 2002 (67 FR 4164), February 7, 2002 (67 FR 5845), March 18, 2002 (67 FR 12042), May 22, 2002 (67 FR 36017), May 16, 2003 (68 FR 26640), April 12, 2004 (69 FR 19211), and August 22, 2011 (76 FR 52340) (referred to collectively in this Notice as the “prior Notices.”). The requirements of the prior Notices continue to apply, except as modified by this Notice.<sup>1</sup>

LMDC administers CDBG-DR funds allocated to the organization for emergency expenses and economic revitalization in response to the September 11, 2001, terrorist attacks in New York City. LMDC is charged with assisting New York City in recovering from the terrorist attacks on the World

Trade Center (WTC), in part by working with the Port Authority of New York and New Jersey (Port Authority). There are two components to this effort. The first is a “Memorial Program,” carried out by LMDC, that includes the construction of a Memorial and Memorial Museum (completed), and the planning and construction of other Memorial-related improvements to complement further redevelopment in the immediate area. The second component is a “Redevelopment Program,” carried out by the Port Authority, which includes commercial and retail space, open space areas, and other improvements. LMDC works closely with the Port Authority to effectuate the Redevelopment Program. For additional information regarding the roles and responsibilities of LMDC and the Port Authority and the World Trade Center Memorial and Cultural Program General Project Plan (GPP), please refer to the LDMC Web site at: [http://www.renewnyc.com/ThePlan/general\\_project\\_plan.asp](http://www.renewnyc.com/ThePlan/general_project_plan.asp).

Consistent with its approved CDBG-DR action plan and amendments, LMDC used CDBG-DR funds to acquire and clear real property identified in the GPP as 130 Liberty Street and 140 Liberty Street. In order to enable LDMC to fully implement its Memorial Program and to enable the Port Authority to pursue its Redevelopment Program, LMDC proposes an exchange of real property interests with the Port Authority. The Port Authority will provide LMDC or its designee with a lease (up to 99 years) and purchase option for Port Authority-owned property that will be used for memorial and cultural facilities that are part of LMDC’s Memorial Program, most specifically a performing arts center. This ownership structure will parallel a prior plan governing the site of the Memorial Museum, which was also part of the larger exchange of memorial and cultural properties dedicated for the Memorial Program. In the first phase of this exchange, the Port Authority will obtain title to the portions of 130 and 140 Liberty Street parcels necessary to finalize the below-grade WTC Vehicle Security Center with a public park, known as Liberty Park, at and above street level, and the St. Nicholas National Shrine at the World Trade Center, all of which are part of the Redevelopment Program. These portions of 130 and 140 Liberty Street have already been partially redeveloped by the Port Authority pursuant to an access agreement with LMDC. HUD must waive certain regulations applicable to the reuse of 130 and 140 Liberty Street to facilitate the current exchange

<sup>1</sup> Links to the prior notices, the text of the Appropriations Act, and additional guidance prepared by the Department for CDBG-DR grants are available on the HUD Exchange Web site: <https://www.hudexchange.info/cdbg-dr/cdbg-drlaws-regulations-and-federal-register-notices/>.

between LMDC and the Port Authority and future development of the rest of the 130 Liberty Street site. The current transfer of property to the Port Authority explicitly excludes that portion of 130 Liberty Street that is labeled as "Tower 5" on Attachment 1 to the GPP as LMDC will retain the Tower 5 site for future transfer and redevelopment.

The proposed property exchange is a step toward finalizing a new site for St. Nicholas Greek Orthodox Church (St. Nicholas), which was destroyed by the collapse of the South Tower of the World Trade Center on September 11, 2001. St. Nicholas had been located at 155 Cedar Street, which is adjacent to the 130 and 140 Liberty Street parcels, but the WTC Memorial and Redevelopment Plan provides for reconstruction of St. Nicholas (as the St. Nicholas National Shrine at the World Trade Center) on a portion of 130 Liberty Street. To carry out this plan, the Port Authority entered into an agreement with St. Nicholas that will permit the Port Authority to acquire 155 Cedar Street from St. Nicholas in exchange for a long-term lease and purchase agreement on a portion of 130 Liberty Street.

As discussed below, reliable valuations of these properties are difficult to obtain but some components of the overall transaction can be evaluated in a more traditional manner. One such component involves the property interest that St. Nicholas will receive from the Port Authority in exchange for 155 Cedar Street. LMDC has carried out an analysis and determined that the properties are comparable, in part due to a permanent restrictive declaration limiting development of the property that will be transferred to St. Nicholas.

As part of the larger planned exchange between the Port Authority and LMDC, LMDC is transferring to the Port Authority the portions of 130 and 140 Liberty Street parcels necessary to finalize the WTC Vehicle Security Center, Liberty Park, and the St. Nicholas National Shrine at the World Trade Center. This transfer will not be considered to be CDBG-assisted and, therefore, will not be subject to CDBG requirements. As a result, the Port Authority's conveyance of a portion of 130 Liberty Street to St. Nicholas for the St. Nicholas National Shrine at the World Trade Center will not be assisted with CDBG-DR funds. Additionally, the Port Authority's proposed use of 155 Cedar Street and the portion of 130 and 140 Liberty Street that it receives from LMDC (minus the St. Nicholas transfer

site) will not be subject to CDBG requirements.

HUD notes that LMDC never intended to retain long-term ownership of 130 and 140 Liberty Street. The properties were purchased with CDBG-DR funds to address conditions that developed as a result of the collapse of the Towers and to obtain open space adjacent to the World Trade Center site. Neither LMDC nor its parent organization, ESDC, holds real property for the long-term and it is LMDC's intention to transfer ownership of its holdings on the World Trade Center site in the future for eligible uses in support of long-term recovery.

## II. Applicable Rules, Statutes, Waivers, and Alternative Requirements

The Appropriation Acts authorize the Secretary to waive, or specify alternative requirements for, any provision of any statute or regulation that the Secretary administers in connection with the obligation by the Secretary or use by the recipient of these grant funds, except for requirements related to fair housing, nondiscrimination, labor standards, and the environment, upon a finding that such waiver is required to facilitate the use of such funds, and would not be inconsistent with the overall purpose of the statute or regulation. Regulatory waiver authority is also provided by 24 CFR 5.110, 91.600, and 570.5.

The following waiver and alternative requirement (together with previously granted waivers and alternative requirements) is necessary to facilitate the use of these funds, and is not inconsistent with the overall purposes of the regulation or title I of the Housing and Community Development Act of 1974, as amended (42 U.S.C. 5301 *et seq.*). Under the requirements of the Appropriations Acts, waivers and alternative requirements must be published in the **Federal Register** no later than 5 days before the effective date of such waiver.

### 1. Waiver To Allow the Lower Manhattan Development Corporation (LMDC) To Transfer Property Acquired and Cleared With CDBG-DR Funds in Exchange for Other Property Interests

Because the 130 and 140 Liberty Street parcels were acquired and cleared using CDBG-DR funds, LMDC's use of these parcels is subject to the CDBG "change of use of real property" provision at 24 CFR 570.489(j), which prohibits grantees from changing the use or planned use of a property acquired with CDBG-DR funds unless the new use of the property qualifies as meeting a national objective, or the grantee reimburses its program in the amount of the current fair market value of the

property. This regulatory provision does not accommodate unique aspects present in LMDC's charge to undertake the Memorial Program and cooperate with the Port Authority in its implementation of the Redevelopment Program, and the realities associated with redevelopment of a nationally significant site in the heart of Lower Manhattan. For these reasons, the Department has determined that good cause exists to grant a waiver of 24 CFR 570.489(j) and establish an alternative requirement to facilitate the use of LMDC's CDBG-DR funds, allow the proposed property exchanges, and promote completion of the Memorial and Redevelopment Programs.

As an alternative requirement, HUD will permit LMDC to compensate its CDBG-DR program for funds expended on acquisition and clearance of 130 and 140 Liberty Street through acquisition (via long-term lease and purchase) of properties on the World Trade Center site from the Port Authority that are sufficient as sites for various memorial and cultural facilities, including the September 11 Memorial and Museum and the yet to be built performing arts center, as described in the GPP and LMDC's applicable Action Plan, as amended. The Department's decision is based on its finding that the properties involved in this transfer present unique valuation difficulties. The portions of 130 and 140 Liberty Street that LMDC will transfer will not be redeveloped for commercial uses but will serve public and non-profit purposes. Given that these parcels are located in Lower Manhattan, their value as commercial properties would be substantial but use for public and non-profit purposes alters their valuation. As a result, common appraisal approaches are not applicable to establishing current fair market valuations. Concurrently, the World Trade Center site is unique and venerated by the city and state of New York as well as the nation as a result of the tragedy that transpired on September 11, 2001. This status makes it exceptionally difficult, if not impossible, to establish reliable valuations of the real property interests on the World Trade Center site that are to be conveyed to LMDC. The difficulties in establishing current fair market valuations of the various parts of this transaction and the strong desire of all parties (including HUD) to facilitate redevelopment progress on and adjacent to the World Trade Center site more than fifteen years after the events of September 11, 2001, create a situation in which the waiver and alternative

requirement represent the most practical and feasible path forward.

HUD finds that good cause exists to waive 24 CFR 570.489(j) and impose an alternative requirement to the extent necessary to allow LMDC to transfer the portions of 130 and 140 Liberty Street necessary to finalize the WTC Vehicle Security Center, Liberty Park, and the St. Nicholas National Shrine at the World Trade Center to the Port Authority without reimbursing the CDBG-DR program for the fair market value of the properties. HUD is therefore waiving section 570.489(j) for this purpose and establishing an alternative requirement to permit LMDC to acquire from the Port Authority property on the World Trade Center site, via long-term lease and purchase, sufficient to carry out the memorial and cultural facilities on the World Trade Center site that are contemplated in the GPP and LMDC's applicable Action Plan, as amended. Additionally, the property to be acquired by LMDC on the World Trade Center site will be subject to CDBG-DR programmatic requirements upon transfer to LMDC. HUD recognizes the phased nature of the transactions contemplated by various parties pursuant to this alternative requirement. However, as part of this alternative requirement, if LMDC does not acquire property that is sufficient to carry out the memorial and cultural facilities on the World Trade Center site as contemplated in the GPP and LMDC's applicable Action Plan, as amended, before LMDC closes out its grants, HUD may pursue appropriate remedial actions.

This waiver and alternative requirement are consistent with the provisions of the Appropriation Acts and are necessary to facilitate LMDC's use of CDBG-DR funds for its Memorial Program.

### III. Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers for the disaster recovery grants under this Notice is 14.218 and 14.228.

### VI. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban

Development, 451 7th Street, SW., Room 10276, Washington, DC 20410-0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202-708-3055 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

Dated: January 9, 2017.

**Nani Coloretti,**

*Deputy Secretary.*

[FR Doc. 2017-00710 Filed 1-13-17; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5968-D-01]

### Order of Succession for the Office of Strategic Planning and Management

**AGENCY:** Office of Strategic Planning and Management, HUD.

**ACTION:** Notice of Order of Succession.

**SUMMARY:** In this notice, the Director of the Office of Strategic Planning and Management for the Department of Housing and Urban Development designates the Order of Succession for the Office of Strategic Planning and Management. This Order of Succession supersedes all prior Orders of Succession for the Office of Strategic Planning and Management.

**DATES:** *Effective Date:* January 10, 2017.  
**FOR FURTHER INFORMATION CONTACT:** Henry Hensley, Director, Office of Strategic Planning and Management, Department of Housing and Urban Development, 451 7th Street SW., Room 10162, Washington, DC 20410, telephone number (202) 402-4360 (this is not a toll free number). Persons with hearing or speech impairments may access this number by calling the toll free Federal Relay Service at (800) 877-8339.

**SUPPLEMENTARY INFORMATION:** The Director of the Office of Strategic Planning and Management for the Department of Housing and Urban Development is issuing this Order of Succession of officials authorized to perform the functions and duties of the Director of the Office of Strategic Planning and Management when, by reason of absence, disability, or vacancy in office, the Director is not available to exercise the powers or perform the duties of the office. This Order of Succession is subject to the provisions of the Federal Vacancies Reform Act of

1998 (5 U.S.C. 3345-3349d). This Order of Succession supersedes all prior Orders of Succession for the Office of Strategic Planning and Management.

Accordingly, the Director of the Office of Strategic Planning and Management designates the following Order of Succession:

### Section A. Order of Succession

During any period when, by reason of absence, disability, or vacancy in office, Director of the Office of Strategic Planning and Management for the Department of Housing and Urban Development is not available to exercise the powers or perform the duties of the Director of the Office of Strategic Planning and Management, the following officials within the Office of Strategic Planning and Management are hereby designated to exercise the powers and perform the duties of the Office. No individual who is serving in an office listed below in an acting capacity may act as the Director of the Office of Strategic Planning and Management pursuant to this Order of Succession.

- (1) Chief Risk Officer
- (2) Deputy Performance Improvement Officer;
- (3) Division Director—Grants Management and Oversight;
- (4) Division Director—Transformation;
- (5) Division Director—Operations.

These officials shall perform the functions and duties of the office in the order specified herein, and no official shall serve unless all the other officials, whose position titles precede his/hers in this order, are unable to act by reason of absence, disability, or vacancy in office.

### Section B. Authority Superseded

This Order of Succession supersedes all prior Orders of Succession for the Office of Strategic Planning and Management.

**Authority:** Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 10, 2017.

**Henry Hensley,**

*Director, Office of Strategic Planning and Management.*

[FR Doc. 2017-00878 Filed 1-13-17; 8:45 am]

**BILLING CODE 4210-67-P**

**DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service**

[Docket No. FWS-HQ-IA-2017-0003;  
FXIA1671090000-178-FF09A30000]

**Endangered Species; Receipt of Applications for Permit**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

**DATES:** We must receive comments or requests for documents on or before February 16, 2017.

**ADDRESSES: Submitting Comments:** You may submit comments by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS-HQ-IA-2017-0003.

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS-HQ-IA-2017-0003; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041-3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

*Viewing Comments:* Comments and materials we receive will be available for public inspection on <http://www.regulations.gov>, or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041-3803; telephone 703-358-2095.

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2281 (fax); [DMAFR@fws.gov](mailto:DMAFR@fws.gov) (email).

**SUPPLEMENTARY INFORMATION:****I. Public Comment Procedures**

*A. How do I request copies of applications or comment on submitted applications?*

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

*B. May I review comments submitted by others?*

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**II. Background**

To help us carry out our conservation responsibilities for affected species, and

in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, “Delivering an Efficient, Effective, and Accountable Government,” and the President’s Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

**III. Permit Applications***Endangered Species*

*Applicant:* New Mexico State University, Las Cruces, NM; PRT-15671C

The applicant requests a permit to import biological samples of wild blue-throated macaw (*Ara glaucogularis*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 1-year period.

*Applicant:* Columbia University, Center for Infection and Immunity, New York, NY; PRT-07998C

The applicant requests a permit to import 563 thick-billed parrot samples (*Rhynchopsitta pachyrhyncha*) from Mexico for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 1-year period.

*Applicant:* Cyler Conrad, Albuquerque, NM; PRT-09206C

The applicant requests a permit to import bone samples from deceased wild collected Galapagos giant tortoise (*Chelonoidis niger*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

*Multiple Applicants*

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

*Applicant:* Charles Waibel, Powell Butte, OR; PRT-12500C

*Applicant:* Richard Killion,  
Breckenridge, TX; PRT-06382C

**Brenda Tapia,**

*Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.*

[FR Doc. 2017-00755 Filed 1-13-17; 8:45 am]

**BILLING CODE 4333-15-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

[178A2100DD/AAKC001030/  
A0A501010.999900253G]

**Land Acquisitions; Craig Tribal Association, Craig, Alaska**

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of final agency determination.

**SUMMARY:** The Principal Deputy Assistant Secretary—Indian Affairs made a final agency determination to acquire 1.08 acres, more or less, of land in trust for the Craig Tribal Association, Alaska, for economic development and other purposes on January 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Helen Riggs, Director, Office of Trust Services, Bureau of Indian Affairs, MS-4620 MIB, 1849 C Street NW., Washington, DC 20240, telephone (202) 208-5831.

**SUPPLEMENTARY INFORMATION:** This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Office of the Assistant Secretary—Indian Affairs by 209 Departmental Manual 8.1, and is published to comply with the requirements of 25 CFR 151.12 (c)(2)(ii) that notice of the decision to acquire land in trust be promptly provided in the **Federal Register**.

On January 10, 2017, the Principal Deputy Assistant Secretary—Indian Affairs issued a decision to accept approximately 1.08 acres, more or less, of land in trust for the Craig Tribal Association, Alaska, under the authority of the Indian Reorganization Act of 1934, 25 U.S.C. 465.

The Alaska Regional Director, on behalf of the Secretary of the Interior, will immediately acquire title in the name of the United States of America in trust for the Craig Tribal Association upon fulfillment of Departmental requirements.

**Legal Description**

The 1.08 acres, more or less, are located in the city of Craig, State of Alaska, and are described as follows:

Lot Q-3, subdivision of the unsubdivided remainder of Tract Q, U.S. Survey 2327, according to the plat thereof filed December 7, 1988, as plat No. 88-39, Ketchikan Recording District, State of Alaska, containing 1.08 acres.

Dated: January 10, 2017.

**Lawrence S. Roberts,**

*Principal Deputy Assistant Secretary—Indian Affairs.*

[FR Doc. 2017-00872 Filed 1-13-17; 8:45 am]

**BILLING CODE 4337-15-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

[178A2100DD/AAKC001030/  
A0A501010.999900 253G]

**Indian Entities Recognized and Eligible To Receive Services From the United States Bureau of Indian Affairs**

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice publishes the current list of 567 Tribal entities recognized and eligible for funding and services from the Bureau of Indian Affairs (BIA) by virtue of their status as Indian Tribes. The list is updated from the notice published on May 4, 2016 (81 FR 26826).

**FOR FURTHER INFORMATION CONTACT:** Ms. Laurel Iron Cloud, Bureau of Indian Affairs, Division of Tribal Government Services, Mail Stop 4513-MIB, 1849 C Street NW., Washington, DC 20240. Telephone number: (202) 513-7641.

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to Section 104 of the Act of November 2, 1994 (Pub. L. 103-454; 108 Stat. 4791, 4792), and in exercise of authority delegated to the Assistant Secretary—Indian Affairs under 25 U.S.C. 2 and 9 and 209 DM 8.

Published below is an updated list of federally acknowledged Indian Tribes in the contiguous 48 states and Alaska, to reflect various name changes and corrections.

Amendments to the list include name changes and name corrections. To aid in identifying tribal name changes and corrections, the Tribe's previously listed or former name is included in parentheses after the correct current tribal name. We will continue to list the Tribe's former or previously listed name for several years before dropping the former or previously listed name from the list.

The listed Indian entities are acknowledged to have the immunities and privileges available to federally recognized Indian Tribes by virtue of

their government-to-government relationship with the United States as well as the responsibilities, powers, limitations, and obligations of such Tribes. We have continued the practice of listing the Alaska Native entities separately solely for the purpose of facilitating identification of them and reference to them given the large number of complex Native names.

Dated: January 10, 2017.

**Lawrence S. Roberts,**

*Principal Deputy Assistant Secretary—Indian Affairs.*

**Indian Tribal Entities Within the Contiguous 48 States Recognized and Eligible To Receive Services From the United States Bureau of Indian Affairs**

Absentee-Shawnee Tribe of Indians of Oklahoma  
 Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California  
 Ak-Chin Indian Community (previously listed as the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona)  
 Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas)  
 Alabama-Quassarte Tribal Town  
 Alturas Indian Rancheria, California  
 Apache Tribe of Oklahoma  
 Arapaho Tribe of the Wind River Reservation, Wyoming  
 Aroostook Band of Micmacs (previously listed as the Aroostook Band of Micmac Indians)  
 Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana  
 Augustine Band of Cahuilla Indians, California (previously listed as the Augustine Band of Cahuilla Mission Indians of the Augustine Reservation)  
 Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin  
 Bay Mills Indian Community, Michigan  
 Bear River Band of the Rohnerville Rancheria, California  
 Berry Creek Rancheria of Maidu Indians of California  
 Big Lagoon Rancheria, California  
 Big Pine Paiute Tribe of the Owens Valley (previously listed as the Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California)  
 Big Sandy Rancheria of Western Mono Indians of California (previously listed as the Big Sandy Rancheria of Mono Indians of California)  
 Big Valley Band of Pomo Indians of the Big Valley Rancheria, California  
 Bishop Paiute Tribe (previously listed as the Paiute-Shoshone Indians of the Bishop Community of the Bishop Colony, California)

- Blackfeet Tribe of the Blackfeet Indian Reservation of Montana
- Blue Lake Rancheria, California
- Bridgeport Indian Colony (previously listed as the Bridgeport Paiute Indian Colony of California)
- Buena Vista Rancheria of Me-Wuk Indians of California
- Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon)
- Cabazon Band of Mission Indians, California
- Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California
- Caddo Nation of Oklahoma
- Cahto Tribe of the Laytonville Rancheria
- Cahuilla Band of Indians (previously listed as the Cahuilla Band of Mission Indians of the Cahuilla Reservation, California)
- California Valley Miwok Tribe, California
- Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California
- Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California)
- Catawba Indian Nation (aka Catawba Tribe of South Carolina)
- Cayuga Nation
- Cedarville Rancheria, California
- Chemehuevi Indian Tribe of the Chemehuevi Reservation, California
- Cher-Ae Heights Indian Community of the Trinidad Rancheria, California
- Cherokee Nation
- Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma)
- Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota
- Chicken Ranch Rancheria of Me-Wuk Indians of California
- Chippewa Cree Indians of the Rocky Boy's Reservation, Montana (previously listed as the Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana)
- Chitimacha Tribe of Louisiana
- Citizen Potawatomi Nation, Oklahoma
- Cloverdale Rancheria of Pomo Indians of California
- Cocopah Tribe of Arizona
- Coeur D'Alene Tribe (previously listed as the Coeur D'Alene Tribe of the Coeur D'Alene Reservation, Idaho)
- Cold Springs Rancheria of Mono Indians of California
- Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California
- Comanche Nation, Oklahoma
- Confederated Salish and Kootenai Tribes of the Flathead Reservation
- Confederated Tribes and Bands of the Yakama Nation
- Confederated Tribes of Siletz Indians of Oregon (previously listed as the Confederated Tribes of the Siletz Reservation)
- Confederated Tribes of the Chehalis Reservation
- Confederated Tribes of the Colville Reservation
- Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians
- Confederated Tribes of the Goshute Reservation, Nevada and Utah
- Confederated Tribes of the Grand Ronde Community of Oregon
- Confederated Tribes of the Umatilla Indian Reservation (previously listed as the Confederated Tribes of the Umatilla Reservation, Oregon)
- Confederated Tribes of the Warm Springs Reservation of Oregon
- Coquille Indian Tribe (previously listed as the Coquille Tribe of Oregon)
- Cortina Indian Rancheria (previously listed as the Cortina Indian Rancheria of Wintun Indians of California)
- Coushatta Tribe of Louisiana
- Cow Creek Band of Umpqua Tribe of Indians (previously listed as the Cow Creek Band of Umpqua Indians of Oregon)
- Cowlitz Indian Tribe
- Coyote Valley Band of Pomo Indians of California
- Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota
- Crow Tribe of Montana
- Death Valley Timbi-sha Shoshone Tribe (previously listed as the Death Valley Timbi-Sha Shoshone Band of California)
- Delaware Nation, Oklahoma
- Delaware Tribe of Indians
- Dry Creek Rancheria Band of Pomo Indians, California (previously listed as the Dry Creek Rancheria of Pomo Indians of California)
- Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada
- Eastern Band of Cherokee Indians
- Eastern Shawnee Tribe of Oklahoma
- Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (previously listed as the Shoshone Tribe of the Wind River Reservation, Wyoming)
- Elem Indian Colony of Pomo Indians of the Sulphur Bank Rancheria, California
- Elk Valley Rancheria, California
- Ely Shoshone Tribe of Nevada
- Enterprise Rancheria of Maidu Indians of California
- Ewiiapaayp Band of Kumeyaay Indians, California
- Federated Indians of Graton Rancheria, California
- Flandreau Santee Sioux Tribe of South Dakota
- Forest County Potawatomi Community, Wisconsin
- Fort Belknap Indian Community of the Fort Belknap Reservation of Montana
- Fort Bidwell Indian Community of the Fort Bidwell Reservation of California
- Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California
- Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon
- Fort McDowell Yavapai Nation, Arizona
- Fort Mojave Indian Tribe of Arizona, California & Nevada
- Fort Sill Apache Tribe of Oklahoma
- Gila River Indian Community of the Gila River Indian Reservation, Arizona
- Grand Traverse Band of Ottawa and Chippewa Indians, Michigan
- Greenville Rancheria (previously listed as the Greenville Rancheria of Maidu Indians of California)
- Grindstone Indian Rancheria of Wintun-Wailaki Indians of California
- Guidiville Rancheria of California
- Habematolel Pomo of Upper Lake, California
- Hannahville Indian Community, Michigan
- Havasupai Tribe of the Havasupai Reservation, Arizona
- Ho-Chunk Nation of Wisconsin
- Hoh Indian Tribe (previously listed as the Hoh Indian Tribe of the Hoh Indian Reservation, Washington)
- Hoopa Valley Tribe, California
- Hopi Tribe of Arizona
- Hopland Band of Pomo Indians, California (formerly Hopland Band of Pomo Indians of the Hopland Rancheria, California)
- Houlton Band of Maliseet Indians
- Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona
- Iipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation)
- Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California
- Ione Band of Miwok Indians of California
- Iowa Tribe of Kansas and Nebraska
- Iowa Tribe of Oklahoma
- Jackson Band of Miwok Indians (previously listed as the Jackson Rancheria of Me-Wuk Indians of California)
- Jamestown S'Klallam Tribe
- Jamul Indian Village of California
- Jena Band of Choctaw Indians



- Jicarilla Apache Nation, New Mexico  
Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona  
Kalispel Indian Community of the Kalispel Reservation  
Karuk Tribe (previously listed as the Karuk Tribe of California)  
Kashia Band of Pomo Indians of the Stewarts Point Rancheria, California  
Kaw Nation, Oklahoma  
Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo)  
Keweenaw Bay Indian Community, Michigan  
Kialegee Tribal Town  
Kickapoo Traditional Tribe of Texas  
Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas  
Kickapoo Tribe of Oklahoma  
Kiowa Indian Tribe of Oklahoma  
Klamath Tribes  
Koi Nation of Northern California (previously listed as the Lower Lake Rancheria, California)  
Kootenai Tribe of Idaho  
La Jolla Band of Luiseno Indians, California (previously listed as the La Jolla Band of Luiseno Mission Indians of the La Jolla Reservation)  
La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California  
Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin  
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin  
Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan  
Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada  
Little River Band of Ottawa Indians, Michigan  
Little Traverse Bay Bands of Odawa Indians, Michigan  
Lone Pine Paiute-Shoshone Tribe (previously listed as the Paiute-Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California)  
Los Coyotes Band of Cahuilla and Cupeno Indians, California (previously listed as the Los Coyotes Band of Cahuilla & Cupeno Indians of the Los Coyotes Reservation)  
Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada  
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota  
Lower Elwha Tribal Community (previously listed as the Lower Elwha Tribal Community of the Lower Elwha Reservation, Washington)  
Lower Sioux Indian Community in the State of Minnesota  
Lummi Tribe of the Lummi Reservation  
Lytton Rancheria of California  
Makah Indian Tribe of the Makah Indian Reservation  
Manchester Band of Pomo Indians of the Manchester Rancheria, California (previously listed as the Manchester Band of Pomo Indians of the Manchester-Point Arena Rancheria, California)  
Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California  
Mashantucket Pequot Indian Tribe (previously listed as the Mashantucket Pequot Tribe of Connecticut)  
Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.)  
Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan  
Mechoopda Indian Tribe of Chico Rancheria, California  
Menominee Indian Tribe of Wisconsin  
Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California  
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico  
Miami Tribe of Oklahoma  
Micosaukee Tribe of Indians  
Middletown Rancheria of Pomo Indians of California  
Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band)  
Mississippi Band of Choctaw Indians  
Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada  
Mohegan Tribe of Indians of Connecticut (previously listed as Mohegan Indian Tribe of Connecticut)  
Mooretown Rancheria of Maidu Indians of California  
Morongo Band of Mission Indians, California (previously listed as the Morongo Band of Cahuilla Mission Indians of the Morongo Reservation)  
Muckleshoot Indian Tribe (previously listed as the Muckleshoot Indian Tribe of the Muckleshoot Reservation, Washington)  
Narragansett Indian Tribe  
Navajo Nation, Arizona, New Mexico & Utah  
Nez Perce Tribe (previously listed as the Nez Perce Tribe of Idaho)  
Nisqually Indian Tribe (previously listed as the Nisqually Indian Tribe of the Nisqually Reservation, Washington)  
Nooksack Indian Tribe  
Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana  
Northfork Rancheria of Mono Indians of California  
Northwestern Band of the Shoshone Nation (previously listed as Northwestern Band of Shoshoni Nation and the Northwestern Band of Shoshoni Nation of Utah (Washakie))  
Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.)  
Oglala Sioux Tribe (previously listed as the Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota)  
Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan)  
Omaha Tribe of Nebraska  
Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin)  
Oneida Nation of New York  
Onondaga Nation  
Otoe-Missouria Tribe of Indians, Oklahoma  
Ottawa Tribe of Oklahoma  
Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes (formerly Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes))  
Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada  
Pala Band of Mission Indians (previously listed as the Pala Band of Luiseno Mission Indians of the Pala Reservation, California)  
Pamunkey Indian Tribe  
Pascua Yaqui Tribe of Arizona  
Paskenta Band of Nomlaki Indians of California  
Passamaquoddy Tribe  
Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California  
Pawnee Nation of Oklahoma  
Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California  
Penobscot Nation (previously listed as the Penobscot Tribe of Maine)  
Peoria Tribe of Indians of Oklahoma  
Picayune Rancheria of Chukchansi Indians of California  
Pinoleville Pomo Nation, California (previously listed as the Pinoleville Rancheria of Pomo Indians of California)  
Pit River Tribe, California (includes XL Ranch, Big Bend, Likely, Lookout, Montgomery Creek and Roaring Creek Rancherías)  
Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama)  
Pokagon Band of Potawatomi Indians, Michigan and Indiana  
Ponca Tribe of Indians of Oklahoma

- Ponca Tribe of Nebraska
- Port Gamble S'Klallam Tribe (previously listed as the Port Gamble Band of S'Klallam Indians)
- Potter Valley Tribe, California
- Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas)
- Prairie Island Indian Community in the State of Minnesota
- Pueblo of Acoma, New Mexico
- Pueblo of Cochiti, New Mexico
- Pueblo of Isleta, New Mexico
- Pueblo of Jemez, New Mexico
- Pueblo of Laguna, New Mexico
- Pueblo of Nambe, New Mexico
- Pueblo of Picuris, New Mexico
- Pueblo of Pojoaque, New Mexico
- Pueblo of San Felipe, New Mexico
- Pueblo of San Ildefonso, New Mexico
- Pueblo of Sandia, New Mexico
- Pueblo of Santa Ana, New Mexico
- Pueblo of Santa Clara, New Mexico
- Pueblo of Taos, New Mexico
- Pueblo of Tesuque, New Mexico
- Pueblo of Zia, New Mexico
- Puyallup Tribe of the Puyallup Reservation
- Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada
- Quartz Valley Indian Community of the Quartz Valley Reservation of California
- Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona
- Quileute Tribe of the Quileute Reservation
- Quinault Indian Nation (previously listed as the Quinault Tribe of the Quinault Reservation, Washington)
- Ramona Band of Cahuilla, California (previously listed as the Ramona Band or Village of Cahuilla Mission Indians of California)
- Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin
- Red Lake Band of Chippewa Indians, Minnesota
- Redding Rancheria, California
- Redwood Valley or Little River Band of Pomo Indians of the Redwood Valley Rancheria California (previously listed as the Redwood Valley Rancheria of Pomo Indians of California)
- Reno-Sparks Indian Colony, Nevada
- Resighini Rancheria, California
- Rincon Band of Luiseno Mission Indians of the Rincon Reservation, California
- Robinson Rancheria (previously listed as the Robinson Rancheria Band of Pomo Indians, California and the Robinson Rancheria of Pomo Indians of California)
- Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota
- Round Valley Indian Tribes, Round Valley Reservation, California (previously listed as the Round Valley Indian Tribes of the Round Valley Reservation, California)
- Sac & Fox Nation of Missouri in Kansas and Nebraska
- Sac & Fox Nation, Oklahoma
- Sac & Fox Tribe of the Mississippi in Iowa
- Saginaw Chippewa Indian Tribe of Michigan
- Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York)
- Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona
- Samish Indian Nation (previously listed as the Samish Indian Tribe, Washington)
- San Carlos Apache Tribe of the San Carlos Reservation, Arizona
- San Juan Southern Paiute Tribe of Arizona
- San Manuel Band of Mission Indians, California (previously listed as the San Manuel Band of Serrano Mission Indians of the San Manuel Reservation)
- San Pasqual Band of Diegueno Mission Indians of California
- Santa Rosa Band of Cahuilla Indians, California (previously listed as the Santa Rosa Band of Cahuilla Mission Indians of the Santa Rosa Reservation)
- Santa Rosa Indian Community of the Santa Rosa Rancheria, California
- Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California
- Santee Sioux Nation, Nebraska
- Sauk-Suiattle Indian Tribe
- Sault Ste. Marie Tribe of Chippewa Indians, Michigan
- Scotts Valley Band of Pomo Indians of California
- Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations))
- Seneca Nation of Indians (previously listed as the Seneca Nation of New York)
- Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma)
- Shakopee Mdewakanton Sioux Community of Minnesota
- Shawnee Tribe
- Sherwood Valley Rancheria of Pomo Indians of California
- Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California
- Shinnecock Indian Nation
- Shoalwater Bay Indian Tribe of the Shoalwater Bay Indian Reservation (previously listed as the Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation, Washington)
- Shoshone-Bannock Tribes of the Fort Hall Reservation
- Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada
- Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota
- Skokomish Indian Tribe (previously listed as the Skokomish Indian Tribe of the Skokomish Reservation, Washington)
- Skull Valley Band of Goshute Indians of Utah
- Snoqualmie Indian Tribe (previously listed as the Snoqualmie Tribe, Washington)
- Soboba Band of Luiseno Indians, California
- Sokaogon Chippewa Community, Wisconsin
- Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado
- Spirit Lake Tribe, North Dakota
- Spokane Tribe of the Spokane Reservation
- Squaxin Island Tribe of the Squaxin Island Reservation
- St. Croix Chippewa Indians of Wisconsin
- Standing Rock Sioux Tribe of North & South Dakota
- Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington)
- Stockbridge Munsee Community, Wisconsin
- Summit Lake Paiute Tribe of Nevada
- Suquamish Indian Tribe of the Port Madison Reservation
- Susanville Indian Rancheria, California
- Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington)
- Sycuan Band of the Kumeyaay Nation
- Table Mountain Rancheria of California
- Tejon Indian Tribe
- Te-Moak Tribe of Western Shoshone Indians of Nevada (Four constituent bands: Battle Mountain Band; Elko Band; South Fork Band and Wells Band)
- The Chickasaw Nation
- The Choctaw Nation of Oklahoma
- The Modoc Tribe of Oklahoma
- The Muscogee (Creek) Nation
- The Osage Nation (previously listed as the Osage Tribe)
- The Quapaw Tribe of Indians
- The Seminole Nation of Oklahoma
- Thlopthlocco Tribal Town
- Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota
- Tohono O'odham Nation of Arizona
- Tolowa Dee-ni' Nation (previously listed as the Smith River Rancheria, California)
- Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York)

- Tonkawa Tribe of Indians of Oklahoma  
 Tonto Apache Tribe of Arizona  
 Torres Martinez Desert Cahuilla Indians, California (previously listed as the Torres-Martinez Band of Cahuilla Mission Indians of California)  
 Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation, Washington)  
 Tule River Indian Tribe of the Tule River Reservation, California  
 Tunica-Biloxi Indian Tribe  
 Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California  
 Turtle Mountain Band of Chippewa Indians of North Dakota  
 Tuscarora Nation  
 Twenty-Nine Palms Band of Mission Indians of California  
 United Auburn Indian Community of the Auburn Rancheria of California  
 United Keetoowah Band of Cherokee Indians in Oklahoma  
 Upper Sioux Community, Minnesota  
 Upper Skagit Indian Tribe  
 Ute Indian Tribe of the Uintah & Ouray Reservation, Utah  
 Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah)  
 Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, California  
 Walker River Paiute Tribe of the Walker River Reservation, Nevada  
 Wampanoag Tribe of Gay Head (Aquinnah)  
 Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community & Washoe Ranches)  
 White Mountain Apache Tribe of the Fort Apache Reservation, Arizona  
 Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma  
 Wilton Rancheria, California  
 Winnebago Tribe of Nebraska  
 Winnemucca Indian Colony of Nevada  
 Wiyot Tribe, California (previously listed as the Table Bluff Reservation—Wiyot Tribe)  
 Wyandotte Nation  
 Yankton Sioux Tribe of South Dakota  
 Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona  
 Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona)  
 Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada  
 Yocha Dehe Wintun Nation, California (previously listed as the Rumsey Indian Rancheria of Wintun Indians of California)  
 Yomba Shoshone Tribe of the Yomba Reservation, Nevada
- Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas)  
 Yurok Tribe of the Yurok Reservation, California  
 Zuni Tribe of the Zuni Reservation, New Mexico
- Native Entities Within the State of Alaska Recognized and Eligible To Receive Services From the United States Bureau of Indian Affairs**
- Agdaagux Tribe of King Cove  
 Akiachak Native Community  
 Akiak Native Community  
 Alatna Village  
 Algaaciq Native Village (St. Mary's)  
 Allakaket Village  
 Alutiiq Tribe of Old Harbor (previously listed as Native Village of Old Harbor and Village of Old Harbor)  
 Angoon Community Association  
 Anvik Village  
 Arctic Village (See Native Village of Venetie Tribal Government)  
 Asa'carsarmiut Tribe  
 Atqasuk Village (Atkasook)  
 Beaver Village  
 Birch Creek Tribe  
 Central Council of the Tlingit & Haida Indian Tribes  
 Chalkyitsik Village  
 Cheesh-Na Tribe (previously listed as the Native Village of Chistochina)  
 Chevak Native Village  
 Chickaloon Native Village  
 Chignik Bay Tribal Council (previously listed as the Native Village of Chignik)  
 Chignik Lake Village  
 Chilkat Indian Village (Klukwan)  
 Chilkoot Indian Association (Haines)  
 Chinik Eskimo Community (Golovin)  
 Chuloonawick Native Village  
 Circle Native Community  
 Craig Tribal Association (previously listed as the Craig Community Association)  
 Curyung Tribal Council  
 Douglas Indian Association  
 Egegik Village  
 Eklutna Native Village  
 Emmonak Village  
 Evansville Village (aka Bettles Field)  
 Galena Village (aka Loudon Village)  
 Gulkana Village  
 Healy Lake Village  
 Holy Cross Village  
 Hoonah Indian Association  
 Hughes Village  
 Huslia Village  
 Hydaburg Cooperative Association  
 Igiugig Village  
 Inupiat Community of the Arctic Slope  
 Iqurmit Traditional Council  
 Ivanof Bay Tribe (previously listed as the Ivanoff Bay Tribe and the Ivanoff Bay Village)  
 Kaguayak Village  
 Kaktovik Village (aka Barter Island)  
 Kasigluk Traditional Elders Council
- Kenaitze Indian Tribe  
 Ketchikan Indian Corporation  
 King Island Native Community  
 King Salmon Tribe  
 Klawock Cooperative Association  
 Knik Tribe  
 Kokhanok Village  
 Koyukuk Native Village  
 Levelock Village  
 Lime Village  
 Manley Hot Springs Village  
 Manokotak Village  
 McGrath Native Village  
 Mentasta Traditional Council  
 Metlakatla Indian Community, Annette Island Reserve  
 Naknek Native Village  
 Native Village of Afognak  
 Native Village of Akhiok  
 Native Village of Akutan  
 Native Village of Aleknagik  
 Native Village of Ambler  
 Native Village of Atka  
 Native Village of Barrow Inupiat Traditional Government  
 Native Village of Belkofski  
 Native Village of Brevig Mission  
 Native Village of Buckland  
 Native Village of Cantwell  
 Native Village of Chenega (aka Chanega)  
 Native Village of Chignik Lagoon  
 Native Village of Chitina  
 Native Village of Chuathbaluk (Russian Mission, Kuskokwim)  
 Native Village of Council  
 Native Village of Deering  
 Native Village of Diomedea (aka Inalik)  
 Native Village of Eagle  
 Native Village of Eek  
 Native Village of Eruk  
 Native Village of Ekwok (previously listed as Ekwok Village)  
 Native Village of Elim  
 Native Village of Eyak (Cordova)  
 Native Village of False Pass  
 Native Village of Fort Yukon  
 Native Village of Gakona  
 Native Village of Gambell  
 Native Village of Gargetown  
 Native Village of Goodnews Bay  
 Native Village of Hamilton  
 Native Village of Hooper Bay  
 Native Village of Kanatak  
 Native Village of Karluk  
 Native Village of Kiana  
 Native Village of Kipnuk  
 Native Village of Kivalina  
 Native Village of Kluti Kaah (aka Copper Center)  
 Native Village of Kobuk  
 Native Village of Kongiganak  
 Native Village of Kotzebue  
 Native Village of Koyuk  
 Native Village of Kwigillingok  
 Native Village of Kwinhagak (aka Quinhagak)  
 Native Village of Larsen Bay  
 Native Village of Marshall (aka Fortuna Ledge)

Native Village of Mary's Igloo  
 Native Village of Mekoryuk  
 Native Village of Minto  
 Native Village of Nanwalek (aka English Bay)  
 Native Village of Napaimute  
 Native Village of Napakiak  
 Native Village of Napaskiak  
 Native Village of Nelson Lagoon  
 Native Village of Nightmute  
 Native Village of Nikolski  
 Native Village of Noatak  
 Native Village of Nuiqsut (aka Nooiksut)  
 Native Village of Nunam Iqua (previously listed as the Native Village of Sheldon's Point)  
 Native Village of Nunapitchuk  
 Native Village of Ouzinkie  
 Native Village of Paimiut  
 Native Village of Perryville  
 Native Village of Pilot Point  
 Native Village of Pitka's Point  
 Native Village of Point Hope  
 Native Village of Point Lay  
 Native Village of Port Graham  
 Native Village of Port Heiden  
 Native Village of Port Lions  
 Native Village of Ruby  
 Native Village of Saint Michael  
 Native Village of Savoonga  
 Native Village of Scammon Bay  
 Native Village of Selawik  
 Native Village of Shaktoolik  
 Native Village of Shishmaref  
 Native Village of Shungnak  
 Native Village of Stevens  
 Native Village of Tanacross  
 Native Village of Tanana  
 Native Village of Tatitlek  
 Native Village of Tazlina  
 Native Village of Teller  
 Native Village of Tetlin  
 Native Village of Tuntutuliak  
 Native Village of Tununak  
 Native Village of Tyonek  
 Native Village of Unalakleet  
 Native Village of Unga  
 Native Village of Venetie Tribal Government (Arctic Village and Village of Venetie)  
 Native Village of Wales  
 Native Village of White Mountain  
 Nenana Native Association  
 New Koliganek Village Council  
 New Stuyahok Village  
 Newhalen Village  
 Newtown Village  
 Nikolai Village  
 Ninilchik Village  
 Nome Eskimo Community  
 Nondalton Village  
 Noorvik Native Community  
 Northway Village  
 Nulato Village  
 Nunakauyarmiut Tribe  
 Organized Village of Grayling (aka Holikachuk)  
 Organized Village of Kake  
 Organized Village of Kasaan

Organized Village of Kwethluk  
 Organized Village of Saxman  
 Orutsarmiut Traditional Native Council (previously listed as Orutsarmiut Native Village (aka Bethel))  
 Oscarville Traditional Village  
 Pauloff Harbor Village  
 Pedro Bay Village  
 Petersburg Indian Association  
 Pilot Station Traditional Village  
 Platinum Traditional Village  
 Portage Creek Village (aka Ohgsenakale)  
 Pribilof Islands Aleut Communities of St. Paul & St. George Islands  
 Qagan Tayagungin Tribe of Sand Point Village  
 Qawalangin Tribe of Unalaska  
 Rampart Village  
 Saint George Island (See Pribilof Islands Aleut Communities of St. Paul & St. George Islands)  
 Saint Paul Island (See Pribilof Islands Aleut Communities of St. Paul & St. George Islands)  
 Seldovia Village Tribe  
 Shageluk Native Village  
 Sitka Tribe of Alaska  
 Skagway Village  
 South Naknek Village  
 Stebbins Community Association  
 Sun'aq Tribe of Kodiak (previously listed as the Shoonaq' Tribe of Kodiak)  
 Takotna Village  
 Tangirnaq Native Village (formerly Lesnoi Village (aka Woody Island))  
 Telida Village  
 Traditional Village of Togiak  
 Tuluksak Native Community  
 Twin Hills Village  
 Ugashik Village  
 Umkumiut Native Village (previously listed as Umkumiute Native Village)  
 Village of Alakanuk  
 Village of Anaktuvuk Pass  
 Village of Aniak  
 Village of Atmautluak  
 Village of Bill Moore's Slough  
 Village of Chefornak  
 Village of Clarks Point  
 Village of Crooked Creek  
 Village of Dot Lake  
 Village of Iliamna  
 Village of Kalskag  
 Village of Kaltag  
 Village of Kotlik  
 Village of Lower Kalskag  
 Village of Ohogamiut  
 Village of Red Devil  
 Village of Salatoff  
 Village of Sleetmute  
 Village of Solomon  
 Village of Stony River  
 Village of Venetie (See Native Village of Venetie Tribal Government)  
 Village of Wainwright  
 Wrangell Cooperative Association  
 Yakutat Tlingit Tribe

Yupit of Andreafski

[FR Doc. 2017-00912 Filed 1-13-17; 8:45 am]

BILLING CODE 4337-15-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLMT9240000-L14400000.ET0000 16X L1109AF; MO# 4500094275; MTM 40614 and MTM 40633]

### Public Land Order No. 7860; Partial Revocation of a Secretarial Order and a Bureau of Reclamation Order; Montana

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Public land order.

**SUMMARY:** This order partially revokes a withdrawal created by a Secretarial Order and a Bureau of Reclamation Order, insofar as they affect 2,643.25 acres withdrawn from the Bureau of Reclamation's Lonesome Lake Reservoir, a sub-unit of the Pick-Sloan Missouri Basin Program. The Bureau of Reclamation has determined that the lands are no longer needed for reclamation purposes.

**DATES:** This public land order is effective on January 17, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Cynthia Eide, Bureau of Land Management, Montana/Dakotas State Office, 5001 Southgate Drive, Billings, Montana 59101-4669; telephone 406-896-5094. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual. FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The Bureau of Reclamation has determined that the lands are no longer needed for reclamation purposes. The revocation is needed to allow for a majority of the lands to be conveyed to the State of Montana under a State Indemnity Selection application. Any lands not conveyed to the State, except 3.25 acres included in an overlapping withdrawal, will be restored to the administration of the Bureau of Land Management. In the event any lands described in Paragraphs 1 and 2 below are not conveyed to the State, those lands will remain segregated from location and entry under the United States mining laws unless later opened by publication of an opening order in accordance with applicable law.

**Order**

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. The Secretarial Order dated October 15, 1904, which withdrew public lands on behalf of the Bureau of Reclamation for the Lonesome Lake Reservoir Site, is hereby partially revoked insofar as it affects the following described lands:

**Principal Meridian, Montana**

- T. 29 N., R. 11 E.,  
 Sec. 21, N $\frac{1}{2}$ NE $\frac{1}{4}$  and N $\frac{1}{2}$ NW $\frac{1}{4}$ ;  
 Sec. 22, NW $\frac{1}{4}$ NW $\frac{1}{4}$ .  
 T. 29 N., R. 12 E.,  
 Sec. 9, W $\frac{1}{2}$  and SE $\frac{1}{4}$ ;  
 Sec. 21, N $\frac{1}{2}$ , SW $\frac{1}{4}$ , N $\frac{1}{2}$ SE $\frac{1}{4}$ , and  
 SW $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
 Sec. 22;  
 Sec. 28, W $\frac{1}{2}$ ;  
 Sec. 29, E $\frac{1}{2}$ NE $\frac{1}{4}$  and E $\frac{1}{2}$ SE $\frac{1}{4}$ .  
 T. 30 N., R. 12 E.,  
 Sec. 35, S $\frac{1}{2}$ SE $\frac{1}{4}$ .

The areas described aggregate 2,480 acres in Chouteau and Hill Counties.

2. The Bureau of Reclamation Order dated March 30, 1950, which withdrew public lands for the Lonesome Lake Reservoir Site, is hereby partially revoked insofar as it affects the following described lands:

**Principal Meridian, Montana**

- T. 29 N., R. 7 E.,  
 Sec. 17, lot 14.  
 T. 29 N., R. 12 E.,  
 Sec. 24, SW $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
 Sec. 25, NW $\frac{1}{4}$ NW $\frac{1}{4}$ .  
 T. 30 N., R. 12 E.,  
 Sec. 35, N $\frac{1}{2}$ SE $\frac{1}{4}$ .

The areas described aggregate 163.25 acres in Chouteau, Hill, and Liberty Counties.

3. All of the lands described in Paragraphs 1 and 2, except for the 80.00 acres described in Paragraph 4 below, are hereby opened for disposal through State Indemnity Selection, but remain segregated from location and entry under the United States mining laws due to a State Indemnity Selection application.

4. At 9 a.m. on February 16, 2017, the following described lands will be restored to management by the Bureau of Land Management and are opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on February 16, 2017, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

**Principal Meridian, Montana**

- T. 29 N., R. 12 E.,  
 Sec. 24, SW $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
 Sec. 25, NW $\frac{1}{4}$ NW $\frac{1}{4}$ .

The areas described aggregate 80.00 acres in Chouteau County.

5. At 9 a.m. on February 16, 2017, the lands described in Paragraph 4 will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provision of existing withdrawals, other segregations of record, and the requirements of applicable law. The lands have been and will remain open to mineral leasing. Appropriation of any of the lands described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempting adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by state law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: January 9, 2017.

**Janice M. Schneider,**  
*Assistant Secretary—Land and Minerals Management.*

[FR Doc. 2017-00835 Filed 1-13-17; 8:45 am]

**BILLING CODE 4310-DN-P**

**DEPARTMENT OF THE INTERIOR****National Park Service**

**[NPS-IMR-GLCA-16773; PPWONRADE2, PMP00E105.YP0000 ]**

**Off-road Vehicle Management Plan, Final Environmental Impact Statement, Glen Canyon National Recreation Area, Arizona and Utah**

**AGENCY:** National Park Service, Interior  
**ACTION:** Notice of availability of the Final Environmental Impact Statement for the Off-road Vehicle Management Plan, Glen Canyon National Recreation Area.

**SUMMARY:** The National Park Service (NPS) announces the availability of a Final Environmental Impact Statement (Plan/FEIS) for the Off-road Vehicle Management Plan, Glen Canyon National Recreation Area (GLCA), located in Arizona and Utah. The Plan/FEIS evaluates the impacts of four action alternatives that address off-road vehicle (ORV) management. It also assesses the impacts that could result

from continuing the current management framework in the no-action alternative.

**DATES:** The NPS will execute a Record of Decision (ROD) no sooner than 30 days following publication by the Environmental Protection Agency of the Notice of Availability of the Final Environmental Impact Statement for the Off-road Vehicle Management Plan.

**ADDRESSES:** The Plan/FEIS will be available in electronic format online through the NPS Planning, Environment, and Public Comment Web site (<http://parkplanning.nps.gov/GLCA>); click on the link to Off-road Vehicle Management Plan/ Environmental Impact Statement. Copies of the Plan/FEIS will also be available at Glen Canyon National Recreation Area Headquarters, 691 Scenic View Drive, Page, Arizona 86040.

**FOR FURTHER INFORMATION CONTACT:** Teri Tucker, Assistant Superintendent, Glen Canyon National Recreation Area, P.O. Box 1507, Page, Arizona 86040, by phone at 928-608-6207, or by email at [teri\\_tucker@nps.gov](mailto:teri_tucker@nps.gov).

**SUPPLEMENTARY INFORMATION:** The purpose of this Plan/FEIS is to evaluate off-road use and on-road all-terrain vehicle (ATV) use and develop management actions that preserve Glen Canyon's scientific, scenic, and historic features; provide for the recreational use and enjoyment of the area; and promote the resources and values for which the area was established as a unit of the national park system. This Plan/FEIS does not adjudicate, analyze, or otherwise determine the validity of R.S. 2477 right-of-way claims.

*The Plan/FEIS evaluates five alternatives:* A no-action alternative (A) and four action alternatives (B, C, D, and E), all of which are summarized below. Alternative E is the NPS preferred alternative. Alternative B is the environmentally preferable alternative. Other alternatives were explored but dismissed from detailed analysis.

- *Alternative A: No-Action.* The no-action alternative represents the status quo and the continuation of existing management policies and actions related to off-road use in Glen Canyon. This alternative is consistent with the Glen Canyon 1979 General Management Plan (GMP) and other planning documents related to off-road travel in Glen Canyon. Under this alternative, conventional motor vehicles would continue to be allowed at 12 accessible shoreline areas—Blue Notch, Bullfrog North and South, Copper Canyon, Crosby Canyon, Dirty Devil, Farley Canyon, Neskahi, Paiute Canyon, Red

Canyon, Stanton Creek, Warm Creek and White Canyon—subject to water level closures. Lone Rock Beach and Lone Rock Play Area would remain open to conventional motor vehicles, street-legal ATVs, and off-highway vehicles (OHV) as defined by state law. Conventional motor vehicles and street legal ATVs would be allowed on GMP roads, with the exception of roads in the Orange Cliffs Management Unit, where ATVs would continue to be prohibited. Off-road use would continue on routes in the Ferry Swale area by all vehicle types. Alternative A does not include safety or noise restrictions and does not include a permit system.

- **Alternative B: No Off-road Vehicle Use.** Under alternative B, off-road use would be managed in a manner consistent with the remote, undeveloped, and lightly traveled nature which characterizes much of Glen Canyon. The isolated and primitive characteristics of the Glen Canyon backcountry would be maintained by limiting the operation of all types of motor vehicles to designated roads. There would be no designated ORV routes or areas. All existing off-road use areas, including the accessible shorelines currently open, Lone Rock Beach, and Lone Rock Beach Play Area, would be closed and restored to natural conditions. Conventional motor vehicles and street-legal ATVs would be allowed on GMP roads, with the exception of roads in the Orange Cliffs Management Unit, where ATVs would continue to be prohibited. All motor vehicles must not exceed a sound level of 96 decibels when operated.

- **Alternative C: Increased Motorized Access.** Under this alternative, off-road use would be managed in a manner that would expand the recreational opportunities in Glen Canyon by increasing the number of ORV routes and areas. Under this alternative, conventional motor vehicles, street-legal ATVs and OHVs, as defined by state law, would be allowed at 15 accessible shorelines—Blue Notch, Bullfrog North and South, Copper Canyon, Crosby Canyon, Dirty Devil, Farley Canyon, Hite Boat Ramp, Neskahi, Nokai Canyon, Piute Canyon, Paiute Farms, Red Canyon, Stanton Creek, Warm Creek and White Canyon—subject to water level closures. Lone Rock Beach and Lone Rock Play Area would be open to conventional motor vehicles, street-legal ATVs and OHVs. The speed limit at the accessible shorelines and Lone Rock Beach would be 15 mph and quiet hours after 10 p.m. would be established. A permit would be required for all off-road travel. A red or orange whip flag would be required at the Lone

Rock Beach Play Area in accordance with Utah OHV regulations. ORV routes would be designated on approximately 22 miles of pre-existing routes in the Ferry Swale area and at other access points across Glen Canyon. Under this alternative conventional motor vehicles, street legal ATVs and OHVs would be allowed on all GMP roads, including on roads in the Orange Cliffs Management Unit. The speed limit on unpaved GMP roads would be 25 mph or as posted. All motor vehicles must not exceed a sound level of 96 decibels when operated.

- **Alternative D: Decreased Motorized Access.** This alternative protects natural and cultural resources by limiting off-road use. Under this alternative, Lone Rock Beach Play Area, Blue Notch, Bullfrog North and South, Copper Canyon, Crosby Canyon, Neskahi, Nokai Canyon, Piute Canyon, Paiute Farms, Red Canyon, Warm Creek and White Canyon would be closed and restored to natural conditions. Conventional motor vehicles would be permitted at four designated accessible shoreline areas, Farley Canyon, Dirty Devil, Hite Boat Ramp and Stanton Creek. Lone Rock Beach would be open only to conventional vehicles. The speed limit at the accessible shorelines and Lone Rock Beach would be 15 mph and quiet hours after 10 p.m. would be established. A permit would be required for all off-road use. No ATVs or OHVs would be allowed in Glen Canyon National Recreation Area. ORV routes would not be designated in the Ferry Swale area or at other access points across Glen Canyon. All motor vehicles must not exceed a sound level of 96 decibels when operated.

- **Alternative E: Mixed Use (NPS Preferred Alternative).** Alternative E is designed to protect resources and enhance the visitor experience by identifying and designating specific areas capable of supporting on-road ATV use and off-road use while prohibiting such uses in areas where resources and values may be at risk. Under this alternative one vehicle-accessible shoreline area—Warm Creek—would be closed permanently. Fourteen areas—Blue Notch, Bullfrog North and South, Copper Canyon, Crosby Canyon, Dirty Devil, Farley Canyon, Hite Boat Ramp, Neskahi, Nokai Canyon, Piute Canyon, Paiute Farms, Red Canyon, Stanton Creek and White Canyon—would remain open to conventional motor vehicles and street-legal ATVs, subject to water-level closures. Lone Rock Beach and Lone Rock Beach Play area would be open to conventional vehicles, street-legal ATVs and OHVs, as defined by state law. The speed limit at the accessible shorelines

and Lone Rock Beach would be 15 mph and quiet hours after 10 p.m. would be established. Lone Rock Beach, Stanton Creek, and other high use areas would include vehicle-free areas. A red or orange whip flag would be required at the Lone Rock Beach Play Area in accordance with Utah OHV regulations. In addition, ORV routes would be designated on approximately 21 miles of pre-existing routes in the Ferry Swale area and at other access points across Glen Canyon. A permit would be required for all off-road use. Under this alternative, conventional motor vehicles, street-legal ATVs and OHVs, as defined by state law, would be allowed on unpaved GMP roads including the Poison Spring Loop in the Orange Cliffs Management Unit. ATVs and OHVs would not be allowed on any other roads in the Orange Cliffs Management Unit. The speed limit on unpaved GMP roads would be 25 mph or as posted. Conventional motor vehicles and street-legal ATVs would be allowed on paved GMP roads, except the Lees Ferry Access Road. All motor vehicles must not exceed a sound level of 96 decibels when operated.

Dated: July 22, 2016.

**Sue E. Masica,**

*Regional Director, Intermountain Region,  
National Park Service.*

**Editorial note:** This document was received for publication by the Office of the Federal Register on January 11, 2017.  
[FR Doc. 2017-00866 Filed 1-13-17; 8:45 am]

**BILLING CODE 4312-52-P**

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## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1020]

### **Certain Industrial Control System Software, Systems Using Same and Components Thereof; Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on a Settlement Agreement; Termination of the Investigation**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

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**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 6) of the presiding administrative law judge (“ALJ”), terminating the above-captioned investigation based on a settlement agreement. The Commission has

determined to terminate the investigation.

**FOR FURTHER INFORMATION CONTACT:**

Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on September 19, 2016, based on a complaint filed on behalf of Rockwell Automation, Inc. of Milwaukee, Wisconsin. 81 FR 64196-97. The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by reason of infringement of the following U.S. Patent Nos.: 6,675,226; 6,816,817; 6,819,960; 6,978,225; 7,130,704; 7,650,196; 7,693,585; and 8,799,800. The complaint further alleged that a domestic industry exists. The Commission's notice of investigation named 3S-Smart Software Solutions, GmbH of Kempten, Germany; Advantech Corporation of Milpitas, California; and Advantech Co., Ltd. of Taipei City, Taiwan as respondents. The Office of Unfair Import Investigations ("OUII") is also a party to the investigation.

On November 15, 2016, the complainant and all respondents jointly moved to terminate the investigation based on a settlement agreement. OUII supported the motion.

The ALJ issued the subject ID on December 15, 2016, granting the motion for termination of the investigation. She found that the motion for termination satisfied Commission Rules 210.21(a)(1), (b)(1) and that termination of the investigation is not contrary to the public interest. She also issued a corrected ID on December 19, 2016, to attach a copy of the settlement agreement. No petitions for review were filed.

The Commission has determined not to review the ID and has terminated the investigation.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: January 10, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2017-00787 Filed 1-13-17; 8:45 am]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—UHD Alliance, Inc.

Notice is hereby given that, on December 22, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), UHD Alliance, Inc. ("UHD Alliance") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, OPPO Digital, Inc., Menlo Park, CA, has been added as a party to this venture. Also, THX Ltd., San Francisco, CA, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UHD Alliance intends to file additional written notifications disclosing all changes in membership.

On June 17, 2015, UHD Alliance filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2015 (80 FR 42537).

The last notification was filed with the Department on September 28, 2016. A notice was published in the **Federal**

**Register** pursuant to Section 6(b) of the Act on October 26, 2016 (81 FR 74481).

**Patricia A. Brink,**

*Director of Civil Enforcement, Antitrust Division.*

[FR Doc. 2017-00892 Filed 1-13-17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF JUSTICE

[OMB Number 1121-0336]

#### Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection: Office for Victims of Crime Training and Technical Assistance Center—Trafficking Information Management System (TIMS)

**AGENCY:** Office for Victims of Crime, Department of Justice.

**ACTION:** 60-Day notice.

**SUMMARY:** The Department of Justice (DOJ), Office of Justice Programs, Office for Victims of Crime, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted for 60 days until March 20, 2017.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Shelby Jones Crawford, Program Manager, Office for Victims of Crime, Office of Justice Programs, Department of Justice, 810 7th Street NW., Washington, DC 20530.

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;



- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision of Existing Collection.
  2. *The Title of the Form/Collection:* Office for Victims of Crime Training and Technical Assistance Center—Trafficking Information Management System (TIMS).
  3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* NA. The applicable component within the Department of Justice is the Office for Victims of Crime, in the Office of Justice Programs.
  4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: OVC Grantees.  
Abstract: The current package for OMB approval is designed to simplify performance reporting for OVC grantees through the OVC Trafficking Information Management System (TIMS) Online system, a Web-based database and reporting system for the Victims of Human Trafficking Grant and the Enhanced Collaborative Model Grant initiatives. OVC will require OVC Grantees to use this electronic tool to submit grant performance data, including demographics about human trafficking victims. Since 2012, OVC has published annual analyses of these data to provide the crime victims' field with stronger evidence for practices and programs.
  5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are approximately 60 OVC Services to Victims of Human Trafficking Grantees per six-month reporting period. On average, it should take each grantee one hour to seven hours, depending on client case load per reporting period, to enter information into TIMS Online. There are two reporting periods per year.
  6. *An estimate of the total public burden (in hours) associated with the collection:* 480 hours (average 60 OVC grantees \* average 4 hours \* 2 times per year).
- If additional information is required contact: Melody Braswell, Department

Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: January 11, 2017.

**Melody Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2017-00794 Filed 1-13-17; 8:45 am]

**BILLING CODE 4410-18-P**

## DEPARTMENT OF LABOR

### Office of the Secretary

#### **Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Law Enforcement Officer's Injury or Occupational Disease and Notice of Law Enforcement Officer's Death**

**ACTION:** Notice.

**SUMMARY:** The Department of Labor is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, "Notice of Law Enforcement Officer's Injury or Occupational Disease and Notice of Law Enforcement Officer's Death," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before February 16, 2017.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201609-1240-001](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201609-1240-001) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or sending an email to [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to

send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Contact Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or sending an email to [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** This ICR seeks approval under the PRA for revisions to the Notice of Law Enforcement Officer's Injury or Occupational Disease and Notice of Law Enforcement Officer's Death information collection. Form CA-721, Notice of Law Enforcement Officer's Injury or Occupational Disease, and Form CA-722, Notice of Law Enforcement Officer's Death, are used for filing claims for compensation for injury and death to non-Federal law enforcement officers under Federal Employees' Compensation Act (FECA) provisions that provide compensation for law enforcement officers not employed by the U.S. killed or injured while apprehending persons suspected of committing Federal crimes. *See* 5 U.S.C. 8191 *et seq.* The forms provide the basic information needed to process the claims made for injury or death. This information collection has been classified as a revision, because accommodation language was added to the form and the instructions page. The FECA authorizes this information collection. *See* 5 U.S.C. 8193.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240-0022. The DOL notes that existing information collection requirements submitted to the OMB continue in effect while they undergo review; however, new requirements would only take effect upon OMB approval. For additional substantive

information about this ICR, see the related notice published in the **Federal Register** on October 5, 2016 (81 FR 69087).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240-0022. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Agency:* DOL-OWCP.

*Title of Collection:* Notice of Law Enforcement Officer's Injury or Occupational Disease and Notice of Law Enforcement Officer's Death.

*OMB Control Number:* 1240-0022.

*Affected Public:* Individuals or Households.

*Total Estimated Number of Respondents:* 7.

*Total Estimated Number of Responses:* 7.

*Total Estimated Annual Time Burden:* 9 hours.

*Total Estimated Annual Other Costs Burden:* \$4.

*Authority:* 44 U.S.C. 3507(a)(1)(D).

Dated: January 10, 2017.

**Michel Smyth,**

*Departmental Clearance Officer.*

[FR Doc. 2017-00806 Filed 1-13-17; 8:45 am]

**BILLING CODE 4510-CH-P**

## NATIONAL CREDIT UNION ADMINISTRATION

### Sunshine Act Meeting

**TIME AND DATE:** 10:00 a.m., Thursday, January 19, 2017.

**PLACE:** Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314-3428.

**STATUS:** Open.

#### MATTERS TO BE CONSIDERED:

1. NCUA's Rules and Regulations, Alternative Capital.
2. Board Briefing, Statutory Inflation Adjustment of Civil Money Penalties.

#### FOR FURTHER INFORMATION CONTACT:

Gerard Poliquin, Secretary of the Board, Telephone: 703-518-6304.

**Gerard Poliquin,**

*Secretary of the Board.*

[FR Doc. 2017-01015 Filed 1-12-17; 4:15 pm]

**BILLING CODE 7535-01-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2016-0158]

### Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft NUREG; extension of comment period.

**SUMMARY:** On December 16, 2016, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on draft NUREG-1556, Volume 21, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator." The public comment period was originally scheduled to close on January 20, 2017. The NRC has decided to extend the public comment period to allow more time for members of the public to develop and submit their comments.

**DATES:** The due date of comments requested in the document published on December 16, 2016 (81 FR 91206) is extended. Comments should be filed no later than February 24, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0158. Address

questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

#### FOR FURTHER INFORMATION CONTACT:

Robert MacDougall, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-5175; email:

[Robert.MacDougall@nrc.gov](mailto:Robert.MacDougall@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Obtaining Information and Submitting Comments

#### A. Obtaining Information

Please refer to Docket ID NRC-2016-0158 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0158.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The draft NUREG-1556, Volume 21, Revision 1, is available in ADAMS under Accession No. ML16336A536.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

The draft NUREG-1556, Volume 21, Revision 1, is also available on the NRC's public Web site on: (1) The "Consolidated Guidance About Materials Licenses (NUREG-1556)" page at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>;

and (2) the “Draft NUREG-Series Publications for Comment” page at <http://www.nrc.gov/public-involve/doc-comment.html#nuregs>.

### B. Submitting Comments

Please include Docket ID NRC–2016–0158 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

## II. Discussion

On December 16, 2016, the NRC solicited comments on draft NUREG–1556, Volume 21, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator.”

The purpose of the document published on December 16, 2016 (81 FR 91206) was to provide the public an opportunity to review and comment on draft NUREG–1556, Volume 21, Revision 1. This NUREG provides guidance both to current holders of possession licenses for radioactive material produced in an accelerator and to persons preparing applications for such licenses. The NUREG also provides the NRC criteria for evaluating a license application.

The public comment period was originally scheduled to close on January 20, 2017. The NRC has decided to extend the public comment period on this document until February 24, 2016, to allow more time for members of the public to submit their comments.

Dated at Rockville, Maryland, this 9th day of January 2017.

For the U.S. Nuclear Regulatory Commission.

**Daniel S. Collins,**

*Director, Division of Material Safety, State, Tribal, and Rulemaking, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2017–00907 Filed 1–13–17; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

[NRC–2017–0002]

### Biweekly Notice: Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Biweekly notice.

**SUMMARY:** Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from December 20, 2016 to December 30, 2016. The last biweekly notice was published on January 3, 2016.

**DATES:** Comments must be filed by February 16, 2017. A request for a hearing must be filed by March 20, 2017.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2017–0002. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladely, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Kay Goldstein, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1506, email: [Kay.Goldstein@nrc.gov](mailto:Kay.Goldstein@nrc.gov).

## I. Obtaining Information and Submitting Comments

### A. Obtaining Information

Please refer to Docket ID NRC–2017–0002 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2017–0002.
- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

### B. Submitting Comments

Please include Docket ID NRC–2017–0002, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should

inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need

to take this action will occur very infrequently.

### A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of

the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by March 20, 2017. The petition must be filed in accordance with the filing instructions in the

“Electronic Submissions (E-Filing)” section of this document, and should meet the requirements for petitions set forth in this section. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

#### *B. Electronic Submissions (E-Filing)*

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC’s E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing

system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC’s public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC’s public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC’s E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC’s Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC’s adjudicatory E-Filing system may seek assistance by contacting the NRC’s Electronic Filing Help Desk through the “Contact Us” link located on the NRC’s public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting

documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC’s electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC’s PDR. For additional direction on accessing information related to this document, see the “Obtaining Information and Submitting Comments” section of this document.

*Duke Energy Progress, LLC, Docket Nos. 50-325 and 50-324, Brunswick Steam Electric Plant, Units 1 and 2 (BSEP), Brunswick County, North Carolina*

*Duke Energy Carolinas, LLC, Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2 (CNS), York County, South Carolina*

*Duke Energy Carolinas, LLC, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2 (MNS), Mecklenburg County, North Carolina*

*Duke Energy Progress, LLC, Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1 (HNP), Wake County, North Carolina*

*Duke Energy Progress, LLC, Docket No. 50-261, H.B. Robinson Steam Electric Plant, Unit No. 2 (RNP), Darlington County, South Carolina*

*Date of amendment request:* September 27, 2016, as supplemented by letter dated November 22, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16273A042 and ML16327A325, respectively.

*Description of amendment request:* The proposed amendments would revise the Technical Specification (TS) Surveillance Requirements (SRs), which currently require operating ventilation systems with charcoal filters for a 10-hour period every 31 days. The SRs would be revised to require operation of the systems for 15 continuous minutes every 31 days. The proposed amendments are consistent with NRC-approved Technical Specifications Task Force (TSTF) Traveler TSTF-522, Revision 0, "Revise Ventilation System Surveillance Requirements to Operate for 10 hours per Month," as published in the **Federal Register** on September 20, 2012 (77 FR 58428), with variations due to plant-specific nomenclature.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's analysis is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change affects various BSEP, CNS, MNS, HNP, and RNP SRs that currently require ventilation systems to be periodically operated for 10 continuous hours. These SRs would be modified to require operation for 15 continuous minutes.

These systems are not accident initiators and therefore, these changes do not involve

a significant increase in the probability of an accident. The proposed system and filter testing changes are consistent with current regulatory guidance for these systems and will continue to assure that these systems perform their design function, which may include mitigating accidents. Thus, the change does not involve a significant increase in the consequences of an accident.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change affects various BSEP, CNS, MNS, HNP, and RNP SRs that currently require ventilation systems to be periodically operated for 10 continuous hours. These SRs would be modified to require operation for 15 continuous minutes.

The change proposed for these ventilation systems does not change any system operations or maintenance activities. Testing requirements will be revised and will continue to demonstrate that the Limiting Conditions for Operation are met and the system components are capable of performing their intended safety functions. The change does not create new failure modes or mechanisms and no new accident precursors are generated.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change affects various BSEP, CNS, MNS, HNP, and RNP SRs that currently require ventilation systems to be periodically operated for 10 continuous hours. These SRs would be modified to require operation for 15 continuous minutes.

The design basis for the BSEP, HNP, and RNP ventilation systems' heaters is to heat the incoming air, thereby reducing the relative humidity. The proposed change will continue to demonstrate that the heaters are capable of heating the air and will perform their design function.

The CNS and MNS ventilation systems are tested at 95 percent relative humidity, and, therefore, do not require heaters to heat the incoming air and reduce the relative humidity.

These proposed changes are consistent with regulatory guidance, and do not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied.

Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Kathryn B. Nolan, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, NC 28202.

*NRC Acting Branch Chief:* Jeanne D. Johnston.

*Duke Energy Progress, LLC, Docket Nos. 50-325 and 50-324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina*

*Date of amendment request:* November 18, 2016. A publicly-available version is in ADAMS under Accession No. ML16343A521.

*Description of amendment request:* The amendment would modify the Technical Specification (TS) definition of Shutdown Margin (SDM) to require calculation of the SDM at a reactor moderator temperature of 68 degrees Fahrenheit (°F), or a higher temperature that represents the most reactive state throughout the operating cycle. This change is needed to address new boiling water reactor (BWR) fuel designs, which may be more reactive at shutdown temperatures above 68 °F. This proposed change is in accordance with the industry Technical Specifications Task Force (TSTF) initiative identified as Change Traveler TSTF-535, Revision 0, "Revise Shutdown Margin Definition to Address Advanced Fuel Designs." The availability of this TS improvement was announced in the **Federal Register** published on February 26, 2013 (78 FR 13100), as part of NRC's Consolidated Line Item Improvement Process.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change revises the definition of SDM. SDM is not an initiator to any accident previously evaluated. Accordingly, the proposed change to the definition of SDM has no effect on the probability of any accident previously evaluated. SDM is an assumption in the analysis of some previously evaluated accidents, and inadequate SDM could lead to an increase in consequences for those accidents. However, the proposed change revises the SDM definition to ensure that the correct SDM is determined for all fuel types at all times during the fuel cycle. As a result, the proposed change does not adversely affect the consequences of any accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change revises the definition of SDM. The change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operations. The change does not alter assumptions made in the safety analysis regarding SDM.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change revises the definition of SDM. The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change ensures that the SDM assumed in determining safety limits, limiting safety system settings or limiting conditions for operation is correct for all BWR fuel types at all times during the fuel cycle.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Kathryn B. Nolan, Deputy General Counsel, 550 South Tryon Street, M/C DEC45A, Charlotte NC 28202.

*NRC Acting Branch Chief:* Jeanne D. Johnston.

*Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1 (FCS), Washington County, Nebraska*

*Date of amendment request:* October 25, 2016. A publicly-available version is in ADAMS under Accession No. ML16299A275.

*Description of amendment request:* This licensee proposes to revise the FCS Updated Safety Analysis Report (USAR) to change the structural design methodology for the Auxiliary Building at FCS. Specifically, the licensee proposes the following changes: (1) Use the ultimate strength design (USD) method from the industry standard American Concrete Institute (ACI) 318-63, "Publication SP-10, Commentary on Building Code Requirements for Reinforced Concrete," for normal operating/service conditions for future designs and evaluations; (2) use higher concrete compressive strength values for Class B concrete, based on original strength test data; (3) use higher reinforcing steel yield strength values,

based on original strength test data; and (4) make minor clarifications, including adding a definition of control fluids to the dead load section of the USAR.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

This LAR [license amendment request] revises the methodology used to re-evaluate or design new modifications to the existing Auxiliary Building. All other structures will continue to utilize the current license basis and thus are not affected by this change. The proposed change allows evaluations of the Auxiliary Building to apply the ultimate strength design (USD) method from the ACI 318-63 Code for normal operating/service load combinations.

The ACI USD method is an accepted industry standard used for the design and analysis of reinforced concrete. A change in the methodology that an analysis uses to verify structure qualifications does not have any impact on the probability of accidents previously evaluated. Designs performed with the ACI USD method will continue to demonstrate that the Auxiliary Building meets industry accepted ACI Code requirements. This LAR does not propose changes to the no loss-of-function loads, loading combinations, or required USD capacity.

The use of increased concrete strength based on original test data for the areas identified in Section 2.3 of this document and the use of higher steel yield strength maintain adequate structural capacity. As such, these proposed changes do not pose a significant increase in the probability or consequences of an accident previously evaluated because the revised strength values are determined based on actual original test data using a high level of confidence.

The controlled hydrostatic load is changed from live load to dead load for USD in the definition. This is consistent with ACI-349-97 [American Concrete Institute Code Requirements for Nuclear Safety Related Concrete Structures] and therefore does not pose a significant increase in the probability or consequences of an accident previously evaluated.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

This LAR proposes no physical change to any plant system, structure, or component. Similarly, no changes to plant operating practices, operating procedures, computer firmware, or computer software are proposed.

This LAR does not propose changes to the design loads used to design Class I structures. Application of the new methodology to the design or evaluation of the Auxiliary Building will continue to ensure the Auxiliary Building will adequately house and protect equipment important to safety.

Calculations that use the ACI USD method for normal operating/service load combinations will continue to demonstrate that the concrete structures meet required design criteria. Use of the increased compressive strength of concrete based on 28-day test data (not age hardening) is permitted by the ACI 318-63 Code and ensures that the concrete structure is capable of performing its design function without alteration or compensatory actions of any kind. A higher steel yield has minimal reduction on design margin. The controlled hydrostatic load is changed from live load to dead load for USD in the definition which is consistent with ACI-349-97.

The use of these alternative methodologies for qualifying the Auxiliary Building does not have a negative impact on the ability of the structure or its components to house and protect equipment important to safety and thus, does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change is for the design of new modifications or re-analysis of the Auxiliary Building.

Utilization of the ACI 318-63 Code USD method applies only to the normal operating/service load cases and is already part of the current license basis (CLB) for no loss-of-function load cases. No changes to design basis loads are proposed; therefore, new designs or re-evaluations of the Auxiliary Building shall still prove capable of coping with design basis loads.

Use of the increased compressive strength of concrete based on 28-day test data is justified and further constrained by limiting its application to areas where the concrete is not exposed to excessive moisture (*i.e.* exterior walls below 1007' [foot] elevation). The use of a higher steel yield is conservatively derived from original test data and has minimal reduction on design margin. The controlled hydrostatic load is changed from live load to dead load for USD in the definition which is consistent with ACI-349-97.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* David A. Repka, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006-3817.

*NRC Branch Chief:* Douglas A. Broadus.



*Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1 (FCS), Washington County, Nebraska*

*Date of amendment request:*

November 18, 2016. A publicly-available version is in ADAMS under Accession No. ML16323A228.

*Description of amendment request:*

The proposed amendment would delete License Condition 3.D., "Fire Protection Program," which requires that FCS implement and maintain a fire protection program that complies with the requirements of 10 CFR 50.48(a) and 10 CFR 50.48(c). Since power operations are terminated at FCS and the reactor is permanently defueled, FCS will maintain a fire protection program in accordance with 10 CFR 50.48(f).

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change removes the Fire Protection License Condition which is applicable to an operating reactor. Because FCS is permanently defueled, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated because: (1) The proposed amendment does not alter, degrade, or prevent action described or assumed in any accident in the USAR [Updated Safety Analysis Report] from being performed, (2) the proposed amendment does not alter any assumptions previously made in evaluating radiological consequences, and (3) the proposed amendment does not affect the integrity of any fission product barrier.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not alter any, safety limits, or safety analysis assumptions associated with the operation of the plant. The proposed change does not introduce any new accident initiators, nor does the change reduce or adversely affect the capabilities of any plant structure or system in the performance of its safety function.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change does not alter the manner in which safety limits or limiting safety system settings are determined. The safety analysis acceptance criteria are not affected by the proposed change. The proposed change does not change the design function of any equipment assumed to operate in the event of an accident.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* David A. Repka, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006-3817.

*NRC Branch Chief:* Douglas A. Broadus.

*PSEG Nuclear LLC, and Exelon Generation Company, LLC, Docket Nos. 50-272 and 50-311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey*

*Date of amendment request:*

November 17, 2016. A publicly-available version is in ADAMS under Accession No. ML16323A279.

*Description of amendment request:*

The amendments would revise the Salem Nuclear Generating Station (Salem), Unit Nos. 1 and 2, Accident Monitoring Instrumentation Technical Specifications (TSs) and Surveillance Requirements by modifying the list of instruments to be operable based on implementation of Regulatory Guide 1.97, Revision 2, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident." In addition, the amendments would revise the allowed outage times and required actions for inoperable channels to be consistent with NUREG-1431, Revision 4, "Standard Technical Specifications—Westinghouse Plants." TS 6.9.4, "Special Reports," would also be revised to reflect these changes.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below with NRC staff edits in square brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed changes to the TS modify Accident Monitoring Instrumentation TS Tables 3.3-11 and 4.3-11 of Salem Units

and 2 by removing or adding instruments as listed [in the amendment request], and updating the AOT [allowed outage time] and required actions to better align with the Westinghouse STS [Standard Technical Specifications], NUREG-1431. The instruments listed [in the amendment request] are not assumed to be initiators of any analyzed event of Chapter 15 in the Updated Final Safety Analysis Report (UFSAR). Therefore the probability of an accident previously evaluated is not significantly increased.

The proposed changes do not alter the design of any system, structure, or component (SSC). The proposed changes conform to NRC regulatory guidance regarding the content of plant TS, as identified in 10 CFR 50.36, NUREG-1431, and the NRC Final Policy Statement in 58 FR 39132.

TS Operability requirements are retained for Type A and Category 1 variables. Operability of these instruments ensures sufficient information is available to monitor and assess plant status during and following an accident. Alternate means for diagnosing and responding to instrument malfunctions are unaffected by the proposed change. Therefore, the consequences of an accident previously evaluated are not significantly increased.

Therefore, these proposed changes do not represent a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed changes to the TS would modify the TS Tables 3.3-11 and 4.3-11 of Salem Units 1 and 2, by removing or adding instruments as listed [in the amendment request], and updating the AOT and required actions to better align with the Westinghouse STS. The proposed changes do not involve a modification to the physical configuration of the plant or changes in the methods governing normal plant operation. The proposed changes will not impose any new or different requirement or introduce a new accident initiator, accident precursor, or malfunction mechanism.

Additionally, there is no change in the types or increases in the amounts of any effluent that may be released off-site and there is no increase in individual or cumulative occupational exposure.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

*Response:* No.

The proposed changes to the TS would modify the TS Tables 3.3-11 and 4.3-11 of Salem Units 1 and 2, by removing or adding instruments as listed [in the amendment request], and updating the AOT and required actions to better align with the Westinghouse STS. The instruments removed from Tables 3.3-11 and 4.3-11 are not needed for manual operator action necessary for safety systems

to accomplish their safety function for the design basis events. The instruments listed for removal are indication-only with the exception of containment pressure narrow range instruments; thus, they do not provide an input to any automatic trip functions. In the case where similar or related instruments (e.g., containment pressure-narrow range) are associated with important trips (i.e., RPS or ESF trips), such instruments are governed by separate existing TS sections which are not altered by this request.

Therefore, since the proposed changes do not impact the response of the plant to a design basis accident, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jeffrie J. Keenan, PSEG Nuclear LLC—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

*NRC Acting Branch Chief:* Stephen S. Koenick.

*PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey*

*Date of amendment request:* May 11, 2016, as supplemented by letter dated December 13, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16132A374 and ML16348A017, respectively.

*Description of amendment request:* The amendment would revise the Hope Creek Generating Station Technical Specification (TS) requirements by deleting TS Action Statement 3.4.2.1.b concerning stuck open safety/relief valves. In addition, TS 3.6.2.1 Action Statements regarding suppression chamber water temperature would be revised to align with NUREG–1433, Revision 4, “Standard Technical Specifications—General Electric Plants (BWR/4).”

The license amendment request was original noticed in the **Federal Register** on July 19, 2016 (81 FR 46965). The notice is being reissued in its entirety to include the revised scope, description of the amendment request, and proposed no significant hazards consideration determination.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided, in its December 13, 2016, letter, its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or

consequences of an accident previously evaluated?

*Response:* No.

The proposed TS change deletes Action Statement 3.4.2.1.b concerning safety/relief valves and revises TS Action Statement 3.6.2.1.b to be consistent with the BWR Standard Technical Specifications (NUREG–1433, “Standard Technical Specifications General Electric Plants, BWR/4,” Revision 4, dated April 2012). The two (2) minute action represents detailed methods of responding to an event, and therefore, if eliminated, would not result in increasing the probability of the event, nor act as an initiator of an event. Limiting condition for operation 3.6.2.1, “Depressurization Systems—Suppression Chamber,” and plant procedures provide operators with appropriate direction for response to a suppression pool high temperature (which could be caused by a stuck open relief valve). Providing specific direction to close the valve within two (2) minutes does not provide additional plant protection beyond what is provided for in plant procedures and TS 3.6.2.1.

Therefore, this action can be eliminated, and will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed TS change deletes Action Statement 3.4.2.1.b concerning safety/relief valves and revises TS Action Statement 3.6.2.1.b to be consistent with the BWR Standard Technical Specifications (NUREG–1433, “Standard Technical Specifications General Electric Plants, BWR/4,” Revision 4, dated April 2012). This change does not change the design or configuration of the plant. No new operation or failure modes are created, nor is a system-level failure mode created that is different than those that already exist.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change does not involve a significant reduction in a margin of safety, nor does it affect any analytical limits. There are no changes to accident or transient core thermal hydraulic conditions, or fuel or reactor coolant boundary design limits, as a result of the proposed change. The proposed change will not alter the assumptions or results of the analysis contained in the Updated Final Safety Analysis Report (UFSAR).

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the

amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jeffrie J. Keenan, PSEG Nuclear LLC—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

*NRC Acting Branch Chief:* Stephen S. Koenick.

*Tennessee Valley Authority, Docket No. 50–391, Watts Bar Nuclear Plant (WBN), Unit 2, Rhea County, Tennessee*

*Date of amendment request:*

November 23, 2016. A publicly-available version is in ADAMS under Accession No. ML16333A250.

*Description of amendment request:* The amendment would revise Technical Specification (TS) Surveillance Requirement (SR) 3.0.2 to extend, on a one-time basis, certain SRs that are normally performed on an 18-month frequency in conjunction with a refueling outage. The proposed change extends the due date for these SRs to October 31, 2017, which allows these SRs to be performed during the first refueling outage for WBN Unit 2.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The requested action is a one-time extension to the performance interval of a limited number of TS surveillance requirements. The performance of these surveillances, or the extension of these surveillances, is not a precursor to an accident. Performing these surveillances or failing to perform these surveillances does not affect the probability of an accident. Therefore, the proposed delay in performance of the SRs in this amendment request does not increase the probability of an accident previously evaluated.

A delay in performing these surveillances does not result in a system being unable to perform its required function. In the case of this one-time extension request, the short period of additional time that the systems and components will be in service before the next performance of the surveillance will not affect the ability of those systems to operate as designed. Therefore, the systems required to mitigate accidents will remain capable of performing their required function. No new failure modes have been introduced because of this action and the consequences remain consistent with previously evaluated accidents. On this basis, the proposed delay in performance of the SRs in this amendment request does not involve a significant increase in the consequences of an accident.

Therefore, the proposed change does not involve a significant increase in the

probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any previously evaluated?

*Response:* No.

The proposed amendment does not involve a physical alteration of any system, structure, or component (SSC) or a change in the way any SSC is operated. The proposed amendment does not involve operation of any SSCs in a manner or configuration different from those previously recognized or evaluated. No new failure mechanisms will be introduced by the one-time SR extensions being requested.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The proposed amendment is a one-time extension of the performance interval of a limited number of TS surveillance requirements. Extending these surveillance requirements does not involve a modification of any TS limiting conditions for operation. Extending these SRs does not involve a change to any limit on accident consequences specified in the license or regulations. Extending these SRs does not involve a change in how accidents are mitigated or a significant increase in the consequences of an accident. Extending these SRs does not involve a change in a methodology used to evaluate consequences of an accident. Extending these SRs does not involve a change in any operating procedure or process.

The instrumentation and components involved in this request have exhibited reliable operation based on current test results. The current testing includes power ascension testing and surveillance testing that either partially or fully exercised the components. Some components have been evaluated for extended testing intervals greater than 18 months but are set at WBN to an 18-month frequency.

Based on the limited additional period of time that the systems and components will be in service before the surveillances are next performed, as well as the operating experience that these surveillances are typically successful when performed, it is reasonable to conclude that the margins of safety associated with these SRs will not be affected by the requested extension.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration. *Attorney for licensee:* Sherry A. Quirk, Executive Vice President and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Dr., 6A West Tower,

Knoxville, TN 37902. *NRC Acting Branch Chief:* Jeanne D. Johnston.

### III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

*Dominion Nuclear Connecticut, Inc., Docket No. 50-336, Millstone Power Station, Unit No. 2 (MPS2), New London County, Connecticut*

*Date of amendment request:* January 25, 2016, as supplemented by letters dated June 27 and October 12, 2016.

*Brief description of amendment:* The amendment revised the MPS2 technical specifications (TSs) to remove the requirement for the charging pumps to be operable in TS 3.5.2, "Emergency Core Cooling Systems, ECCS Subsystems— $T_{avg} \geq 300$  °F," by

eliminating surveillance requirement 4.5.2.e from the TSs. The proposed change also revises the MPS2 final safety analysis report relative to the long-term analysis of the inadvertent opening of a pressurized water reactor pressurizer pressure relief valve event and clarifies the existing discussion regarding the application of single failure criteria.

*Date of issuance:* December 22, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 90 days from the date of issuance.

*Amendment No.:* 331. A publicly-available version is in ADAMS under Accession No. ML16308A485; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. DPR-65:* Amendment revised the Renewed Facility Operating License.

*Date of initial notice in Federal Register:* May 24, 2016 (81 FR 32804). The supplemental letters dated June 27 and October 12, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 22, 2016.

*No significant hazards consideration comments received:* No.

*Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas*

*Date of application for amendment:* December 22, 2015.

*Brief description of amendment:* The amendment revised the Technical Specifications (TSs) to provide a short Allowed Outage Time to restore an inoperable system for conditions under which the existing TSs require a plant shutdown. The amendment is consistent with TS Task Force (TSTF) traveler TSTF-426 Revision 5, "Revise or Add Actions to Preclude Entry into LCO [Limiting Condition for Operation] 3.0.3—RITSTF [Risk-Informed TSTF] Initiatives 6b & 6c."

*Date of issuance:* December 29, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 90 days from the date of issuance.

*Amendment No.:* 304. A publicly-available version is in ADAMS under Accession No. ML16267A139; documents related to this amendment

are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. NPF-6:* The amendment revised the Renewed Facility Operating License and Technical Specifications.

*Date of initial notice in Federal Register:* February 16, 2016 (81 FR 7838).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 29, 2016.

*No significant hazards consideration comments received:* No.

*Exelon Generation Company, LLC, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania*

*Date of amendment request:* March 29, 2016, as supplemented by letter dated September 6, 2016.

*Brief description of amendments:* The amendments revised the technical specification (TS) requirements for snubbers.

*Date of issuance:* December 29, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 60 days of issuance.

*Amendment Nos.:* 223 and 184. A publicly-available version is in ADAMS under Accession No. ML16335A038; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Renewed Facility Operating License Nos. NPF-39 and NPF-85:* Amendments revised the Renewed Facility Operating Licenses and TSs.

*Date of initial notice in Federal Register:* May 24, 2016 (81 FR 32807). The supplemental letter dated September 6, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 29, 2016.

*No significant hazards consideration comments received:* No.

*Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant (DCPP), Units 1 and 2, San Luis Obispo County, California*

*Date of application for amendments:* October 26, 2011, as supplemented by letters dated December 20, 2011; April 2, April 30, June 6, August 2, September

11, November 27, and December 5, 2012; March 7, March 25, April 30, May 9, May 30, and September 17, 2013; April 24 and April 30, 2014; February 2 and June 22, 2015; and January 25, February 11, and August 17, 2016.

*Brief description of amendments:* The amendments revised the facility operating licenses to allow the permanent replacement of the current DCPD Eagle 21 digital process protection system (PPS) with a new digital PPS that is based on the Invensys Operations Management Tricon Programmable Logic Controller (PLC), Version 10, and the CS Innovations, LLC (a Westinghouse Electric Company), Advanced Logic System. The amendments also incorporate a revised definition of Channel Operational Test in Technical Specification (TS) 1.1, "Definitions."

*Date of issuance:* December 21, 2016.

*Effective date:* This license amendment is effective as of its date of issuance and shall be implemented within 120 days from the date of issuance.

*Amendment Nos.:* Unit 1—227; Unit 2—229. A publicly-available version is in ADAMS under Accession No. ML16139A008; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. DPR-80 and DPR-82:* The amendments revised the Facility Operating Licenses and Technical Specifications.

*Date of initial notice in Federal Register:* June 7, 2016 (81 FR 36606). The supplemental letter dated August 17, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 21, 2016.

*No significant hazards consideration comments received:* No.

*STP Nuclear Operating Company, Docket No. 50-498, South Texas Project, Unit 1, Matagorda County, Texas*

*Date of amendment request:* April 7, 2016, as supplemented by letters dated May 25 and September 28, 2016.

*Brief description of amendment:* The amendment revised Technical Specification 5.3.2, "Control Rod Assemblies," to allow permanent operation with 56 full-length control

rods with no control rod assembly in core location D-6.

*Date of issuance:* December 21, 2016.

*Effective date:* As of the date of issuance and shall be implemented prior to entering Mode 5 from Mode 6 during startup from refueling outage 1RE20.

*Amendment No.:* Unit 1—211. A publicly-available version is in ADAMS under Accession No. ML16319A010; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Facility Operating License No. NPF-76:* The amendment revised the Facility Operating License and Technical Specifications.

*Date of initial notice in Federal Register:* July 19, 2016 (81 FR 46967).

The supplemental letter dated September 28, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 21, 2016.

*No significant hazards consideration comments received:* No.

*ZionSolutions, LLC, Docket Nos. 50-295 and 50-304, Zion Nuclear Power Station, Units 1 and 2, Lake County, Illinois*

*Date of application for amendment:* January 7, 2016, as supplemented by letter dated June 22, 2016, and December 1, 2016.

*Brief description of amendment:* This amendment revises the Zion Nuclear Power Station Licenses to approve the Independent Spent Fuel Installation (ISFSI) only Emergency Plan.

*Date of issuance:* December 20, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 60 days.

*Amendment Nos.:* 190 and 177. A publicly-available version is in ADAMS under Accession No. ML16211A074; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. NPF-39 and NPF-48:* These amendments revise the Licenses.

*Date of initial notice in Federal Register:* March 1, 2016, (81 FR 10683).

The supplemental letters dated June 22, 2016, and December 1, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed,

and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 20, 2016.

*No significant hazards consideration comments received:* No.

#### **IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Public Announcement or Emergency Circumstances)**

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed no significant hazards consideration determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate, and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of

increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License or Combined License, as applicable, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

##### *A. Opportunity To Request a Hearing and Petition for Leave To Intervene*

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendment.

Within 60 days after the date of publication of this notice, any persons

(petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by March 20, 2017. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or federally recognized Indian Tribe, or agency

thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

#### *B. Electronic Submissions (E-Filing)*

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing

system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting



documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

For further details with respect to these license amendment applications,

see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

*Arizona Public Service Company, et al., Docket No. STN 50-530, Palo Verde Nuclear Generating Station, Unit No. 3, Maricopa County, Arizona*

*Date of application for amendment:* December 21, 2016, as supplemented by letter dated December 23, 2016.

*Brief description of amendment:* The emergency amendment revised the Technical Specifications (TSs) for a one-time extension of the emergency diesel generator (DG) completion time described in TS 3.8.1.B.4. Specifically, the emergency amendment extended the TS required action 3.8.1.B.4 completion time from 10 days to 21 days for the purpose of collecting and analyzing data associated with the failure of train B DG and continuing with the repair of the DG. During surveillance testing on December 15, 2016, the DG suffered a failure of the number nine right cylinder connecting rod and piston. Current plans to collect and analyze data associated with the engine failure and continue with the repair will exceed the TS required action completion time of 10 days. As a result, the licensee evaluated the defense-in-depth and compensatory measures and is requesting a one-time deterministic license amendment to extend the completion time based upon the guidance of Standard Review Plan Branch Technical Position 8-8, "Onsite (Emergency Diesel Generators) and Offsite Power Sources Allowed Outage Time Extensions."

*Date of issuance:* December 23, 2016.

*Effective date:* As of the date of issuance and shall be implemented prior to the expiration of the 10-days completion time, or December 25, 2016, at 3:56 a.m. PST.

*Amendment No.:* Unit 3—199. A publicly-available version is in ADAMS under Accession No. ML16358A676; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. NPF-74:* The amendment revised the Operating License and TSs.

*Public comments requested as to Proposed no significant hazards consideration (NSHC):* No.

The Commission's related evaluation of the amendment, finding of emergency circumstances, state consultation, and final NSHC determination are contained

in a safety evaluation dated December 23, 2016.

*Attorney for licensee:* Michael G. Green, Senior Regulatory Counsel, Pinnacle West Capital Corporation, P.O. Box 52034, Mail Station 8695, Phoenix, Arizona 85072-2034.

*NRC Branch Chief:* Robert J. Pascarelli.

*Southern Nuclear Operating Company, Inc., Docket No. 50-425, Vogtle Electric Generating Plant, Unit 2, Burke County, Georgia*

*Date of amendment request:* December 13, 2016.

*Brief description of amendment:* The amendment modifies the Unit 2 Technical Specifications (TS) Limiting Condition for Operation (LCO) 3.7.9, "Ultimate Heat Sink (UHS)," to add a Note to extend the completion time of Condition D.2.2 of LCO 3.7.9 to 77 days to allow for refurbishing the 2A nuclear service cooling water transfer pump. This TS change would be only for the 2A NSCW transfer pump during operating Cycle 19.

*Date of issuance:* December 21, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment No.:* 165. A publicly-available version is in ADAMS under Accession No. ML16354A133; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. NPF-81:* Amendment revised the Renewed Facility Operating License and TSs.

*Public comments requested as to proposed no significant hazards consideration (NSHC):* Yes.

Public notice of the proposed amendment was published in *The Augusta Chronicle*, located in Augusta, Georgia, on December 17 and December 18, 2016. The notice provided an opportunity to submit comments on the Commission's proposed NSHC determination. No Comments were received.

The Commission's related evaluation of the amendment, finding of exigent circumstances, state consultation, public comments, and final NSHC determination are contained in a safety evaluation dated December 21, 2016.

*Attorney for licensee:* Jennifer M. Buettner, Associate General Counsel, Southern Nuclear Operating Company, Inc., 40 Inverness Center Parkway, Birmingham, AL 35242.

*NRC Branch Chief:* Michael T. Markley.

Dated at Rockville, Maryland, this 6th day of January 2017.



For the Nuclear Regulatory Commission.

**George A. Wilson,**

*Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2017-00909 Filed 1-13-17; 8:45 am]

**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2016-0276]

### Category 3 Source Security and Accountability; Correction

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Source protection; public meetings and request for comment; correction.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on January 9, 2017, regarding Category 3 source security and accountability. This action is necessary to delete erroneous text in the paragraph under the heading "IV. Public Comments Process."

**DATES:** The correction is effective January 17, 2017.

**ADDRESSES:** Please refer to Docket ID NRC-2016-0276 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0276. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

### FOR FURTHER INFORMATION CONTACT:

Irene Wu, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-1951; email: [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov).

**SUPPLEMENTARY INFORMATION:** In the FR on January 9, 2017, in FR Doc. 2017-00169, on page 2402, in the first column, the second sentence under the heading "IV. Public Comments Process," is corrected to read as follows: "Responses to this solicitation will inform staff consideration of the regulatory impacts for any recommendations related to Category 3 source security and accountability, which will be documented in a paper to be provided to the Commission in August 2017."

Dated at Rockville, Maryland, this 11th day of January 2017.

For the Nuclear Regulatory Commission.

**Douglas Bollock,**

*Acting Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2017-00822 Filed 1-13-17; 8:45 am]

**BILLING CODE 7590-01-P**

## OFFICE OF SCIENCE AND TECHNOLOGY POLICY

### National Nanotechnology Initiative Meetings

**ACTION:** Notice of public webinars.

**SUMMARY:** The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold one or more webinars to share information with the general public and the nanotechnology research and development community. Topics covered may include technical subjects; environmental, health, and safety issues; business case studies; or other areas of potential interest to the nanotechnology community.

**DATES:** The NNCO will hold one or more webinars between the publication of this Notice and December 31, 2017. The first webinar will be held on or after January 18, 2017.

**ADDRESSES:** For information about upcoming webinars, please visit <http://www.nano.gov/PublicWebinars>. Many webinars will be broadcast via AdobeConnect, which requires the installation of a free plug-in on a computer or of a free app on a mobile device.

*Submitting Questions:* Some webinars may include question-and-answer segments in which questions of interest may be submitted through the webinar interface. During the question-and-answer segments of the webinars, submitted questions will be considered in the order received and may be posted on the NNI Web site (<http://www.nano.gov>). A moderator will identify relevant questions and pose them to the speaker(s). Due to time constraints, not all questions may be addressed during the webinars. The moderator reserves the right to group similar questions and to skip questions, as appropriate. The Public Webinar page on [nano.gov](http://www.nano.gov) (<http://www.nano.gov/PublicWebinars>) will indicate which webinars will include question-and-answer segments.

*Registration:* Registration for the webinars will open approximately two weeks prior to each event and will be capped at 500 participants or as space limitations dictate. Individuals planning to attend a webinar can find registration information at <http://www.nano.gov/PublicWebinars>. Written notices of participation by email should be sent to [sstandridge@nnco.nano.gov](mailto:sstandridge@nnco.nano.gov) or mailed to Stacey Standridge, 4201 Wilson Blvd., Stafford II, Suite 405, Arlington, VA 22230.

**FOR FURTHER INFORMATION CONTACT:** For information regarding this Notice, please contact Stacey Standridge at National Nanotechnology Coordination Office, by telephone (703-292-8103) or email ([sstandridge@nnco.nano.gov](mailto:sstandridge@nnco.nano.gov)).

*Meeting Accommodations:* Individuals requiring special accommodation to access any of these public events should contact Stacey Standridge (telephone 703-292-8103) at least ten business days prior to the meeting so that appropriate arrangements can be made.

**Ted Wackler,**

*Deputy Chief of Staff and Assistant Director.*

[FR Doc. 2017-00790 Filed 1-13-17; 8:45 am]

**BILLING CODE 3270-F7-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. IA-4605/803-00229]

### Brown Advisory LLC; Notice of Application

January 10, 2017.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice of application for an exemptive order under Section 206A of the Investment Advisers Act of 1940

(the “Advisers Act”) and Rule 206(4)–5(e).

**APPLICANT:** Brown Advisory LLC (“Applicant” or “Adviser”).

**RELEVANT ADVISERS ACT SECTIONS:** Exemption requested under section 206A of the Advisers Act and rule 206(4)–5(e) from rule 206(4)–5(a)(1) under the Advisers Act.

**SUMMARY OF APPLICATION:** Applicant requests that the Commission issue an order under section 206A of the Advisers Act and rule 206(4)–5(e) exempting it from rule 206(4)–5(a)(1) under the Advisers Act to permit Applicant to receive compensation from certain government entities for investment advisory services provided to the government entities within the two-year period following a contribution by a covered associate of the Applicant to an official of the government entities.

**FILING DATES:** The application was filed on July 18, 2016, and an amended and restated application was filed on November 22, 2016.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 6, 2017, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission’s Secretary.

**ADDRESSES:** Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicant: Brown Advisory LLC, 901 South Bond Street, Suite 400, Baltimore, MD 21231.

**FOR FURTHER INFORMATION CONTACT:** Vanessa M. Meeks, Senior Counsel, or Parisa Haghshenas, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel’s Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission’s Web site at <http://www.sec.gov/rules/iareleases.shtml> or by calling (202) 551–8090.

### Applicant’s Representations

1. Applicant is a Maryland limited liability company registered with the Commission as an investment adviser under the Advisers Act. Applicant provides discretionary investment advisory services to individuals and institutions.

2. The individual who made the campaign contribution that triggered the two-year compensation ban (the “Contribution”) is Douglas Godine (the “Contributor”). The Contributor is the head of business development for the Adviser’s private client team and has been with the Adviser for five years. The Contributor’s role focuses on oversight of business development for the private client and Outsourced Chief Investment Officer (“OCIO”) teams. Applicant submits that, because the Contributor, in his OCIO role, oversees business development activities related to clients that may include entities covered by Rule 206(4)–5(f)(5), he is a covered associate as defined by Rule 206(4)–5(f)(2)(ii).

3. Seven of the Adviser’s clients are agencies, authorities, or instrumentalities of the State of Maryland (the “Clients”). The Clients are government entities as defined in Rule 206(4)–5(f)(5)(i).

4. The recipient of the Contribution was Larry Hogan (the “Candidate”), who, at the time of the Contribution was the governor-elect of Maryland, and at the time of this Application is Maryland’s Governor. The Maryland Governor is the chief executive of the state and can influence investment decisions, including the hiring of an investment adviser, for the state and for other entities that are overseen by boards composed of individuals appointed by the Maryland Governor (“Gubernatorial Appointees”). Due to his office and the power of appointment, the Maryland Governor is an “official” of the Clients as defined in Rule 206(4)–5(f)(6)(ii). None of the Gubernatorial Appointees serving at the time of the Contribution were appointed by the Candidate, who had not yet taken office.

5. The Contribution that triggered rule 206(4)–5’s prohibition on compensation under rule 206(4)–5(a)(1) was recorded on January 12, 2015, for the amount of \$1,000 made out to “Larry Hogan for Governor.” Applicant submits that the contribution was made by the Contributor for purely personal reasons, separate and apart from the Contributor’s role with the Adviser. The Contribution was made at the request of a family friend with whom the Contributor has been friends for about a

decade. The Contributor and his friend are active together in their local sports community, and they have been active participants together in their children’s sports teams. In the past, the Contributor has provided support for other causes at the request of the friend, including monetary support. The friend invited the Contributor to a dinner at a restaurant in Annapolis for members of the local community. Applicant submits that the Contributor was unaware the event was a fundraiser for the Candidate until he attended the event, and that the Contributor had no prior contact, affiliation with, or intention to contribute to the Candidate. Applicant represents that the Contributor did not seek out or initiate contact with the Candidate and that he was briefly introduced to the Candidate at the event, but at no time was there any mention of the Adviser or the Clients.

6. The Clients’ decisions to invest with the Adviser occurred long before the Candidate commenced his campaign for office in January 2014, before the Candidate was elected in November 2014, and before the Contribution was made in January 2015. The earliest of the Clients made a commitment to invest with the Adviser in 2004, and the most recent Client did so in 2012. Applicant represents that none of the Clients have materially increased the amounts of assets managed by the Adviser, initiated new investment mandates, or opened new accounts with the Adviser since the Contribution was made. The Contributor has had no interaction with the Clients, with any representative of the Clients, or with the Clients’ boards.

7. The Adviser became aware of the Contribution when it conducted a check of campaign contribution disclosures on June 8, 2016. Within one week, the Contributor requested the return of the full Contribution from the Candidate. This request was granted and a check refunding the full Contribution was received on July 15, 2016. After identifying the Contribution, the Adviser took steps beginning on June 8, 2016 to establish an escrow account, and the Adviser has deposited an amount equal to the sum of all fees paid to the Adviser and its affiliates, directly or indirectly, with respect to the Clients since the date of the Contribution, January 12, 2015. Additional fees or other compensation accruing in favor of the Adviser and its affiliates will continue to be deposited into the escrow account or will not be collected from the Clients until it is determined whether exemptive relief will be granted to the Adviser.

8. The Applicant's Political Contributions Policy (the "Policy") was adopted and published in January 2011, before Rule 206(4)–5's compliance date and long before the Contribution was made. All contributions by employees to federal, state, and local office incumbents and candidates are subject to pre-clearance, not post-contribution reporting, under the Policy. There is no *de minimis* exception from pre-clearance for small contributions. Both before and after the Rule's compliance date, the Adviser has conducted a series of compliance training sessions that addressed the Policy, including reiterating the need to pre-clear all political contributions, together with an annual policy compliance attestation by all employees. The Adviser also circulates periodic reminders of the Policy to employees. The compliance testing conducted by the Adviser includes periodic searches of campaign contribution databases for the names of employees, such as the search that identified the Contribution.

#### Applicant's Legal Analysis

1. Rule 206(4)–5(a)(1) under the Advisers Act prohibits a registered investment adviser from providing investment advisory services for compensation to a government entity within two years after a contribution to an official of the government entity is made by the investment adviser or any covered associate of the investment adviser. Each of the Clients is a "government entity," as defined in rule 206(4)–5(f)(5), the Contributor is a "covered associate" as defined in rule 206(4)–5(f)(2), and the Candidate is an "official" as defined in rule 206(4)–5(f)(6).

2. Section 206A of the Advisers Act grants the Commission the authority to "conditionally or unconditionally exempt any person or transaction . . . from any provision or provisions of [the Advisers Act] or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of [the Advisers Act]."

3. Rule 206(4)–5(e) provides that the Commission may exempt an investment adviser from the prohibition under Rule 206(4)–5(a)(1) upon consideration of the factors listed below, among others:

(1) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act;

(2) Whether the investment adviser: (i) Before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of the rule; and (ii) prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and (iii) after learning of the contribution: (A) Has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and (B) has taken such other remedial or preventive measures as may be appropriate under the circumstances;

(3) Whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the investment adviser, or was seeking such employment;

(4) The timing and amount of the contribution which resulted in the prohibition;

(5) The nature of the election (*e.g.*, federal, state or local); and

(6) The contributor's apparent intent or motive in making the contribution which resulted in the prohibition, as evidenced by the facts and circumstances surrounding such contribution.

4. Applicant requests an order pursuant to section 206A and rule 206(4)–5(e), exempting it from the two-year prohibition on compensation imposed by rule 206(4)–5(a)(1) with respect to investment advisory services provided to the Clients within the two-year period following the Contribution.

5. Applicant submits that the exemption is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act. Applicant further submits that the other factors set forth in rule 206(4)–5(e) similarly weigh in favor of granting an exemption to the Applicant to avoid consequences disproportionate to the violation.

6. Applicant contends that given the nature of the Rule violation, and the lack of any evidence that the Adviser or the Contributor intended to, or actually did, interfere with any client's merit-based process for the selection or retention of advisory services, the interests of the Clients are best served by allowing the Adviser and its Clients to continue their relationship uninterrupted. Applicant states that causing the Adviser to serve without compensation for a two-year period could result in a financial loss that is more than 1,949 times the amount of the

Contribution that exceeded the *de minimis* threshold. Applicant suggests that the policy underlying the Rule is served by ensuring that no improper influence is exercised over investment decisions by governmental entities as a result of campaign contributions and not by withholding compensation as a result of unintentional violations.

7. Applicant represents the Policy was adopted and published in January 2011, before the Rule's compliance date and long before the Contribution was made. Applicant further represents that, at all times, the Policy has conformed to the requirements of the Rule and has been even broader than what was contemplated by the Rule. Both before and after the Rule's compliance date, the Adviser has conducted a series of compliance training sessions that addressed the Policy, including reiterating the need to pre-clear all political contributions, together with an annual policy compliance attestation by all employees. The compliance testing conducted by the Adviser includes periodic searches of campaign contribution databases for the names of employees, such as the search that identified the Contribution.

8. Applicant asserts that at no time did any employee of the Adviser other than the Contributor have any knowledge that the Contribution had been made before its discovery by the Adviser in June 2016.

9. Applicant asserts that after learning of the Contribution, the Adviser and the Contributor promptly took steps to obtain a return of the Contribution and to implement additional measures to prevent future error, including providing supplemental training to all employees on the Policy to ensure that other employees fully understand the Policy and do not make the same mistake as the Contributor.

10. Applicant states that after learning of the Contribution, it confirmed that the Contributor had no contact with any representative of the Clients and will have no contact with any representative of the Clients for the duration of the two-year period beginning January 12, 2015.

11. Applicant asserts that the Clients' decisions to invest with the Adviser occurred long before the Candidate commenced his campaign for office in January 2014, before the Candidate was elected in November 2014, and before the Contribution was made in January 2015. Applicant states that, at the time of the Contribution, the Candidate had not exercised or even obtained the appointment power reserved to his State office. The Contributor is a longtime Maryland resident and voter, and

Applicant states that the Contributor's violation of the Policy and the Rule resulted from the Contributor's failure to appreciate the regulatory significance of the Contribution, which was intended as a friendly gesture toward a social acquaintance.

12. Applicant submits that neither the Adviser nor the Contributor sought to interfere with the Clients' merit-based selection process for advisory services, nor did they seek to negotiate higher fees or greater ancillary benefits than would be achieved in arms' length transactions. Applicant further submits that there was no violation of the Adviser's fiduciary duty to deal fairly or disclose material conflicts given the absence of any intent or action by the Adviser or the Contributor to influence the selection process. Applicant contends that in the case of the Contribution, imposition of the two-year prohibition on compensation does not achieve the Rule's purposes and would result in consequences disproportionate to the mistake that was made.

#### Applicant's Conditions

The Applicant agrees that any order of the Commission granting the requested relief will be subject to the following conditions:

1. The Contributor will be prohibited from discussing the business of the Applicant with any "government entity" client for which the Official is an "official," each as defined in Rule 206(4)-5(f), until January 12, 2017.

2. The Contributor will receive a written notification of the conditions and will provide a quarterly certificate of compliance until January 12, 2017. Copies of the certifications will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

3. The Applicant will conduct testing reasonably designed to prevent violations of the conditions of the Order and maintain records regarding such testing, which will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

For the Commission, by the Division of Investment Management, under delegated authority.

**Eduardo A. Aleman,**  
Assistant Secretary.

[FR Doc. 2017-00778 Filed 1-13-17; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79769; File No. SR-BatsEDGX-2017-01]

### Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the Fee Schedule of the Exchange's Options Platform To Adopt Fees for its Recently Adopted Bats Auction Mechanism

January 10, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on January 3, 2017, Bats EDGX Exchange, Inc. ("EDGX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to modify the Fee Schedule applicable to the Exchange's options platform ("EDGX Options") to adopt fees for its recently adopted Bats Auction Mechanism ("BAM", "BAM Auction", or "Auction").<sup>3</sup>

The text of the proposed rule change is available at the Exchange's Web site at [www.bats.com](http://www.bats.com), at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 79718 (January 3, 2017) (SR-BatsEDGX-2016-41), available at: <https://www.sec.gov/rules/sro/batsedgx.shtml>.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

##### Background

The Exchange proposes to modify the Fee Schedule applicable to the Exchange's options platform ("EDGX Options") to adopt fees for its recently adopted Bats Auction Mechanism ("BAM", "BAM Auction", or "Auction"). BAM includes functionality in which a Member (an "Initiating Member") may electronically submit for execution an order it represents as agent on behalf of a Priority Customer,<sup>4</sup> broker dealer, or any other person or entity ("Agency Order") against principal interest or against any other order it represents as agent (an "Initiating Order") provided it submits the Agency Order for electronic execution into the BAM Auction pursuant Rule 21.19. All options traded on EDGX Options are eligible for BAM.

As additional background for the fees described below, the Exchange notes that any person or entity other than the Initiating Member may submit responses to an Auction. A BAM Auction takes into account responses to the Auction as well as interest resting on the Exchange's order book at the conclusion of the auction ("unrelated orders"), regardless of whether such unrelated orders were already present on the Exchange's order book when the Agency Order was received by the Exchange or were received after the Exchange commenced the applicable Auction. If contracts remain from one or more unrelated orders at the time the Auction ends, they will be considered for participation in the BAM order allocation process.

##### Definitions

In connection with the fee proposal, the Exchange proposes to adopt definitions necessary for BAM pricing. First, the Exchange proposes to adopt defined terms of "BAM" and "BAM Auction" to refer to Auctions on the Fee Schedule. Second, the Exchange proposes to adopt the defined term "BAM Agency Order", which would be

<sup>4</sup> The term "Priority Customer" means any person or entity that is not: (A) A broker or dealer in securities; or (B) a Professional. The term "Priority Customer Order" means an order for the account of a Priority Customer. See Rule 16.1(a)(45). A "Professional" is any person or entity that: (A) Is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members. See Rule 16.1(a)(46).

defined as an order represented as agent by a Member on behalf of another party, and submitted to BAM for potential price improvement pursuant to Rule 21.19. Third, the Exchange proposes to adopt the defined term “BAM Contra Order” or “Initiating Order”,<sup>5</sup> which would be defined as an order submitted by a Member entering a BAM Agency Order for execution within BAM, that will potentially execute against the BAM Agency Order pursuant to Rule 21.19. Fourth, the Exchange proposes to adopt the defined term “BAM Customer-to-Customer Immediate Cross”, which would provide a cross-reference to the process defined in Rule 21.19(c).<sup>6</sup> Finally, the Exchange proposes to adopt the defined term “BAM Responder Order”, which would be defined to include any order submitted in response to and specifically designated to participate in a BAM Auction as well as unrelated orders that are received by the Exchange after a BAM Auction has begun.

#### BAM Pricing

The Exchange proposes to adopt six new fee codes in connection with BAM, which would be added to the Fee Codes and Associated Fees table of the Fee Schedule. These fee codes represent the fees applicable to BAM, as described below. In addition, the Exchange proposes to adopt new footnote 6, which would again summarize BAM fees and rebates in a table form, would provide additional details regarding the applicability of such fees and rebates, and would include a provision regarding BAM Break-Up Credits.

The Exchange proposes to adopt two fee codes for BAM Agency Orders, fee code BA and fee code BC, which would be applicable to Non-Customer<sup>7</sup> and Customer<sup>8</sup> orders, respectively. As proposed, the Exchange would apply fee code BA to Non-Customer BAM Agency Orders that are executed in an Auction and would charge such orders a fee of

\$0.20 per contract. The Exchange would apply fee code BC to Customer BAM Agency Orders that are executed in an Auction and would provide such orders a rebate of \$0.14 per contract.

Next, the Exchange proposes to adopt fee code BB, which would apply to a BAM Contra Order executed in an Auction and would be charged a fee of \$0.04 per contract.

The Exchange also proposes to adopt fee codes BD and BE, which would apply to BAM Responder Orders in Penny Pilot Securities<sup>9</sup> and Non-Penny Pilot Securities,<sup>10</sup> respectively. As proposed, the Exchange would apply fee code BD or BE to a BAM Responder Order that is executed in an Auction. The Exchange proposes to charge a fee of \$0.50 per contract for executions yielding fee code BD and to charge a fee of \$1.05 per contract for executions yielding fee code BE.

Finally, the Exchange proposes to adopt fee code CC for all executions in a BAM Customer-to-Customer Immediate Cross. As proposed, all executions yielding fee code CC would be provided free of charge.

As discussed above, in addition to setting forth the proposed fees and rebates in the Fee Codes and Associated Fees table, the Exchange proposes to adopt footnote 6 to again summarize BAM fees and rebates in a table form that is organized differently in order to provide clarity to Users.<sup>11</sup> Footnote 6 would be organized similar to existing footnotes on the Fee Schedule and would first make clear that the footnote is applicable to the following six fee codes: BA, BB, BC, BD, BE and CC. The footnote would then re-state the fees applicable to BAM, including a lead-in to the table that would state that the fees and rates are applicable when a BAM Agency Order trades in a BAM Auction against either a BAM Contra Order or a BAM Responder Order.

The proposed table would horizontally categorize the types of orders that could be executed within BAM, namely “Agency” (*i.e.*, BAM Agency Orders), “Contra” (*i.e.*, BAM Contra Orders) and “Responder” (*i.e.*, BAM Responder Orders). Further, within the Responder category, the Exchange would differentiate between Penny Pilot Securities and Non-Penny

Pilot Securities (whereas it would not for the other two categories because there is no applicable distinction). Vertically, the table would be organized by Customer, Non-Customer and Customer-to-Customer Immediate Cross.

The Exchange also proposes to make clear with respect to BAM Agency Orders that when a BAM Agency Order executes against one or more resting orders that were already on the Exchange’s order book when the BAM Agency Order was received by the Exchange, the BAM Agency Order and the resting order(s) would receive the Standard Fee Rates. Specifically, and as described above, it is possible for unrelated interest that is already present on the Exchange’s order book when a BAM Agency Order is received to be included in an Auction. As proposed, footnote 6 will make clear that this will not alter the fee structure for such execution and instead the Exchange will charge a fee or provide a rebate to each side of the transaction as if it were a transaction occurring on the Exchange’s order book pursuant to the Exchange’s normal order handling methodology and not in BAM. This stands in contrast to BAM Responder Orders, which, as defined, include unrelated orders that are received by the Exchange after a BAM Auction has begun and which would be charged or provided rebates based specifically on BAM pricing.

The Exchange also proposes to make clear with respect to Customer orders that such orders will be charged or provided rebates based on the proposed pricing for BAM (*e.g.*, will yield fee code BC if submitted as a BAM Agency Order, will yield fee code BB if submitted as a BAM Contra Order, etc.) but that fee code CC would be assigned when both the BAM Agency Order and the BAM Contra Order are Customer orders.

In addition, the Exchange proposes to adopt under footnote 6 BAM Break-Up Credits. As proposed, the Exchange will apply a BAM Break-Up Credit to the Member that submitted a BAM Agency Order, including a Member who routed an order to the Exchange with a Designated Give Up (as described in further detail below), when the BAM Agency Order trades with a BAM Responder Order. As proposed, the BAM Break-Up Credit provided with respect to a BAM Auction in a Penny Pilot Security would be \$0.25 per contract and the BAM Break-Up Credit provided with respect to a BAM Auction in a Non-Penny Pilot Security would be \$0.60 per contract.

<sup>5</sup> The Exchange notes that it has proposed to include the term Initiating Order on the Fee Schedule even though it is not currently used elsewhere on the Fee Schedule because this is the term used for a BAM Contra Order within Rule 21.19.

<sup>6</sup> As set forth in Rule 21.19(c), in lieu of the procedures set forth in paragraphs (a) and (b) of Rule 21.10 [sic], an Initiating Member may enter an Agency Order for the account of a Priority Customer paired with an order for the account of a Priority Customer and such paired orders will be automatically executed without an Auction, subject to the conditions set forth in Rule 21.19(c)(1)–(3).

<sup>7</sup> As defined in the Exchange’s Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/).

<sup>8</sup> As defined in the Exchange’s Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/).

<sup>9</sup> The term “Penny Pilot Security” applies to those issues that are quoted pursuant to Exchange Rule 21.5, Interpretation and Policy .01.

<sup>10</sup> The term “Non-Penny Pilot Security” applies to those issues that are not Penny Pilot Securities quoted pursuant to Exchange Rule 21.5, Interpretation and Policy .01.

<sup>11</sup> The term “Users” applies to any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3.

### Tiered Pricing Incentives

In order to encourage the use of BAM, the Exchange proposes to adopt new tiers under footnotes 1 and 2 of the Fee Schedule, which are similar to existing tiers but with an enhanced rebated to incentivize the submission of BAM Agency Orders.

Fee codes PC and NC are currently appended to all Customer orders in Penny Pilot Securities and Non-Penny Pilot Securities, respectively, and result in a standard rebate of \$0.05 per contract. Instead of the standard rebate provided to Customer orders, Members are able to receive enhanced rebates for Customer orders to the extent they satisfy monthly volume criteria. The Exchange currently offers five Customer Volume Tiers pursuant to footnote 1. For instance, pursuant to Customer Volume Tier 5, a Member will receive an enhanced rebate of \$0.21 per contract where the Member has an ADV<sup>12</sup> in: (i) Customer orders equal to or greater than 0.05% of average OCV;<sup>13</sup> and (ii) Customer or Market Maker<sup>14</sup> orders equal to or greater than 0.35% of average OCV. To encourage the entry of BAM Agency Orders to the Exchange, the Exchange proposes to adopt Customer Volume Tier 6, which would be identical to Tier 5 but would instead provide an enhanced rebate of \$0.25 per contract for Customer orders to the extent a Member also has an ADV in BAM Agency Orders equal to or greater than 1 contract (in addition to the volume criteria described above with respect to Tier 5).

Fee codes PM and NM are currently appended to all Market Maker orders in Penny Pilot Securities and Non-Penny Pilot Securities, respectively, and result in a standard fee of \$0.19 per contract. The Market Maker Volume Tiers in footnote 2 consist of seven separate tiers, each providing a reduced fee or rebate to a Member's Market Maker orders that yield fee codes PM or NM upon satisfying the monthly volume criteria required by the respective tier. For instance, pursuant to Market Maker Volume Tier 7, a Member will be charged a reduced fee of \$0.03 per contract where the Member has: (i) Customer orders equal to or greater than 0.05% of average OCV; and (ii) Customer or Market Maker orders equal to or greater than 0.35% of average OCV.

<sup>12</sup> As defined in the Exchange's Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/).

<sup>13</sup> As defined in the Exchange's Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/).

<sup>14</sup> As defined in the Exchange's Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/).

To encourage the entry of BAM Agency Orders to the Exchange, the Exchange proposes to adopt Market Maker Volume Tier 8, which would be identical to Tier 7 but would instead provide a reduced fee of \$0.02 per contract for Market Maker orders to the extent a Member also has an ADV in BAM Agency Orders equal to or greater than 1 contract (in addition to the volume criteria described above with respect to Tier 7).

### Designated Give Up Footnote

Footnote 5 of the Fee Schedule currently specifies that when order is submitted with a Designated Give Up, as defined in Rule 21.12(b)(1), the applicable rebates for such orders when executed on the Exchange (yielding fee code NC or PC)<sup>15</sup> are provided to the Member who routed the order to the Exchange. Pursuant to Rule 21.12, which specifies the process to submit an order with a Designated Give Up, a Member acting as an options routing firm on behalf of one or more other Exchange Members (a "Routing Firm") is able to route orders to the Exchange and to immediately give up the party (a party other than the Routing Firm itself or the Routing Firm's own clearing firm) who will accept and clear any resulting transaction. Because the Routing Firm is responsible for the decision to route the order to the Exchange, the Exchange provides such Member with the rebate when orders that yield fee code NC or PC are executed.

In connection with the adoption of fees applicable to BAM, the Exchange proposes to add new fee code BC to the lead-in sentence of footnote 5 and to append footnote 5 to fee code BC in the Fee Codes and Associated Fees table of the Fee Schedule. In addition, the Exchange proposes to include reference to Routing Firms (*i.e.*, a Member who routed an order to the Exchange with a Designated Give up) in the proposed BAM Break-Up Credit section of footnote 6, to make clear that a Routing Firm will be provided any applicable BAM Break-Up Credits. Similar to the provision of a rebate to a Routing Firm who routed an order to the Exchange to execute directly on the Exchange's order book, the Exchange believes that a Routing Firm that routed a BAM Agency Order to the Exchange should be provided applicable rebates, including any BAM Break-Up Credits, based on the Routing Firm's decision to route the order to the Exchange.

<sup>15</sup> Fee codes NC and PC are appended to Customer orders in Non-Penny Pilot and Penny Pilot Securities, respectively. *Id.*

### Implementation Date

The Exchange proposes to implement the proposed changes immediately.<sup>16</sup>

### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.<sup>17</sup> Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,<sup>18</sup> in that it provides for the equitable allocation of reasonable dues, fees and other charges among Members and other persons using any facility or system which the Exchange operates or controls.

The Exchange's proposal establishes fees and rebates regarding BAM, which promotes price improvement to the benefit of market participants. The Exchange believes that BAM will encourage market participants, and in particular liquidity providers on the Exchange, to compete vigorously to provide opportunities for price improvement in a competitive auction process. The Exchange believes that its proposal will allow the Exchange to recoup the costs associated with BAM while also incentivizing its use.

The Exchange is adopting the proposed fees and rebates at this time because it believes that the associated revenue will allow it to promote and maintain BAM, which is beneficial to market participants.

In sum, the Exchange believes that the proposed fee and rebate structure is designed to promote BAM and, in particular, to attract Customer liquidity, which benefits all market participants by providing additional trading opportunities. This attracts liquidity providers and an increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow originating from other market participants.

Moreover, the Exchange believes that charging market participants, other than Customers, a higher effective rate for certain BAM transactions is reasonable, equitable, and not unfairly discriminatory because these types of market participants are more

<sup>16</sup> The Exchange notes that it previously adopted fee changes effective January 3, 2017, and thus, has not proposed to modify the date of the Fee Schedule. See SR-BatsEDGX-2016-75, available at: [http://www.bats.com/us/options/regulation/rule\\_filings/edgx/](http://www.bats.com/us/options/regulation/rule_filings/edgx/).

<sup>17</sup> 15 U.S.C. 78f.

<sup>18</sup> 15 U.S.C. 78f(b)(4).

sophisticated and have higher levels of order flow activity and system usage. Facilitating this level of trading activity requires a greater amount of system resources than that of Customers, and thus, generates greater ongoing operational costs for the Exchange. The proposed fees and rebates, which are further discussed below, will allow the Exchange to promote and maintain BAM, which is beneficial to market participants.

#### BAM Agency Orders and BAM Contra Orders

With respect to the proposal to adopt a rebate for Customer BAM Agency Orders (\$0.14 per contract) and adopt fees for both Non-Customer BAM Agency Orders (\$0.20 per contract) and all BAM Contra Orders (\$0.04 per contract), the Exchange believes this is reasonable because it encourages participation in BAM by offering rates that are equivalent to or better than most other price improvement auctions offered by other options exchanges.<sup>19</sup> The rebate for Customer BAM Agency Orders is designed to encourage Customer orders entered into BAM, which is reasonable for the reasons further discussed below. The proposed fees for Non-Customer BAM Agency Orders and BAM Contra Orders are also reasonable because the associated revenue will allow the Exchange to promote and maintain BAM, and continue to enhance its services.

Providing Customers a rebate for BAM Agency Orders, while assessing Non-Customers a fee for BAM Agency Orders, is reasonable because of the desirability of Customer activity. The proposed new fees and rebates for BAM are generally intended to encourage greater Customer trade volume to the Exchange. Customer activity enhances liquidity on the Exchange for the benefit of all market participants and benefits all market participants by providing more trading opportunities, which attracts market makers and other liquidity providers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The practice of incentivizing increased Customer order flow through a fee and rebate schedule

<sup>19</sup> See Miami International Securities Exchange, LLC (“MIAX”) Fee Schedule; and Securities Exchange Act Release No. 72943 (August 28, 2014), 80 [sic] FR 52785 (September 4, 2014) (SR-MIAX-2015-45 [sic]) (notice of filing and immediate effectiveness regarding MIAX PRIME). See also, e.g., NYSE MKT LLC (“NYSE Amex Options”) Fee Schedule and NASDAQ OMX BX, Inc. (“BX Options”) Fee Schedule.

in order to attract professional liquidity providers is, and has been, commonly practiced in the options markets, and the Exchange.<sup>20</sup> The proposed fee and rebate schedule similarly attracts Customer order flow.

The proposed fee and rebate schedule is reasonably designed because it is within the range of fees and rebates assessed by other exchanges employing similar fee structures for price improvement mechanisms.<sup>21</sup> Other competing exchanges offer different fees and rebates for agency orders, contra-side orders, and responder orders to the auction in a manner similar to the proposal.<sup>22</sup> Other competing exchanges also charge different rates for transactions in their price improvement mechanisms for customers versus their non-customers in a manner similar to the proposal.<sup>23</sup> As proposed, all applicable fees and rebates are within the range of fees and rebates for executions in price improvement mechanisms assessed by other exchanges that are currently employing similar fee structures for price improvement mechanisms.

The fee and rebate schedule as proposed continues to reflect differentiation among different market participants typically found in options fee and rebate schedules.<sup>24</sup> The Exchange believes that the differentiation is reasonable and notes that unlike others (e.g., Customers) some market participants like EDGX Options Market Makers commit to various obligations. For example, transactions of an EDGX Options Market Maker must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings.<sup>25</sup> Further, all Market Makers are designated as specialists on EDGX Options for all

<sup>20</sup> See Exchanges Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/); see also, e.g., MIAX Fee Schedule, NYSE Amex Options Fee Schedule, Nasdaq Options Market (“NOM”) Fee Schedule.

<sup>21</sup> See MIAX Fee Schedule; and Securities Exchange Act Release No. 72943 (August 28, 2014), 80 [sic] FR 52785 (September 4, 2014) (SR-MIAX-2015-45 [sic]) (notice of filing and immediate effectiveness regarding MIAX PRIME). See also, e.g., NYSE Amex Options Fee Schedule and BX Options Fee Schedule.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> See Exchange’s Fee Schedule, available at: [http://www.bats.com/us/options/membership/fee\\_schedule/edgx/](http://www.bats.com/us/options/membership/fee_schedule/edgx/); see also, e.g., MIAX Fee Schedule, NYSE Amex Options Fee Schedule, BX Options Fee Schedule and NOM Fee Schedule.

<sup>25</sup> See Exchange Rule 22.5, entitled “Obligations of Market Makers”.

purposes under the Act or rules thereunder.<sup>26</sup> For BAM Agency Orders, establishing a rebate for Customer orders and a fee for Non-Customer Orders is equitable and not unfairly discriminatory. This is because the Exchange’s proposal to provide rebates and assess fees will apply the same to all similarly situated participants. Moreover, all similarly situated BAM Agency Orders are subject to the same proposed fee schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory. In addition, the proposed fee for BAM Agency Orders is equitable and not unfairly discriminatory because, while other market participants (Non-Customers) will be assessed a fee, Customers will receive a rebate because an increase in Customer order flow will bring greater volume and liquidity, which benefits all market participants by providing more trading opportunities and tighter spreads.

#### Customer-to-Customer Immediate Cross

With respect to the Customer-to-Customer Immediate Cross, establishing no Customer fee or rebate for either side of the transaction, is also reasonable, equitably allocated and not unreasonably discriminatory because it still encourages the entry of Customer orders to the Exchange while treating, from the Exchange’s perspective, each side of the order neutrally rather than providing one Customer a rebate but charging another Customer a fee.

#### BAM Responder Orders and Other Unrelated Orders

For BAM Responder Orders, establishing that there will be a \$0.50 fee per contract for orders in Penny Pilot Securities and a \$1.05 fee per contract for orders in Non-Penny Pilot Securities, is reasonable because the associated revenue will allow the Exchange to maintain and enhance its services. The proposed fee and rebate schedule is also reasonably designed because it is within the range of fees and rebates assessed by other exchanges employing similar fee structures for price improvement mechanisms.<sup>27</sup> Other competing exchanges offer different fees and rebates for agency orders, contra-side order, and responders to the auction in a manner similar to the proposal.<sup>28</sup>

For BAM Responder Orders, establishing a fee for such orders is equitable and not unfairly

<sup>26</sup> See Exchange Rule 22.2, entitled “Options Market Maker Registration and Appointment”.

<sup>27</sup> See NYSE Amex Options Fee Schedule; see also, e.g., MIAX Fee Schedule and BX Options Fee Schedule.

<sup>28</sup> *Id.*



discriminatory. This is because the Exchange's proposal to assess such fee will apply the same to all participants and will vary only based on whether the security is a Penny Pilot Security or a Non-Penny Pilot Security. Moreover, all BAM Responder Orders are subject to the same proposed fee schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory.

The Exchange further believes its proposal represents a reasonable and equitable allocation of dues and fees in that the proposal would treat an unrelated order as well as a BAM Agency Order that executes against such order differently depending on whether the unrelated order was already resting on the Exchange's order book at the time the BAM Agency Order was received or was received after the BAM Auction had begun.

As proposed, an unrelated order would be considered a BAM Responder Order if received after the BAM Auction had commenced. As a result, both the BAM Agency Order executing against such order and such order itself would be assessed fees and provided rebates according to the proposed BAM pricing. The Exchange believes this is a reasonable and equitable allocation of dues and fees, and is not unreasonably discriminatory, because it ensures that market participants are treated similarly with respect to their executions against BAM Agency Orders. To do otherwise, to the extent fees are higher pursuant to BAM pricing than under the Exchange's Standard Fee Rates, would incentivize a market participant that wishes to participate in an Auction to nonetheless avoid sending orders to the Exchange that are not targeted towards the Auction and instead send orders to the Exchange's order book generally, knowing that such orders would be considered in the Auction anyway.

In contrast, as proposed, to the extent an unrelated order was already present on the Exchange's order book when a BAM Agency Order is received, such unrelated order, if executed in an Auction, as well as the BAM Agency Order against which it trades will be charged a fee or provided a rebate as if the transaction occurred on the Exchange's order book pursuant to the Exchange's normal order handling methodology and not in BAM. The Exchange similarly believes this is a reasonable and equitable allocation of dues and fees, and is not unreasonably discriminatory, because it will ensure that the participant that had established position on the Exchange's order book first, the unrelated order, is not impacted with respect to applicable fees

or rebates despite the later arrival of a BAM Agency Order that commences an Auction.

#### BAM Break-Up Credits

With respect to the proposal to adopt BAM Break-Up Credits, the Exchange believes this is reasonable because it encourages use of BAM by offering pricing that is equivalent to pricing provided pursuant to other price improvement auctions offered by other options exchanges. The proposal to offer BAM Break-Up Credits is reasonably designed because it is within the range of fees and rebates assessed by other exchanges employing similar fee structures for price improvement mechanisms.<sup>29</sup> Further, the proposed BAM Break-Up Credits are reasonable and equitably allocated because such credits are different based on whether the Auction is for a Penny Pilot Security or a Non-Penny Pilot Security, which is the same differentiation applicable to BAM Responder Orders. Thus, the Exchange has based the amount of the Break-Up Credit, in part, on the amount of the fee it will receive with respect to each BAM Responder Order. Finally, the proposed BAM Break-Up Credits are not unreasonably discriminatory because such credits are equally available to all Members submitting BAM Agency Orders to the Exchange.

#### Tiers

Volume-based rebates such as those currently maintained on the Exchange have been widely adopted by options exchanges and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value of an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and introduction of higher volumes of orders into the price and volume discovery processes. The proposed adoption of Customer Volume Tier 6 and Market Maker Volume Tier 8, are each intended to incentivize Members to send additional Customer and Market Maker orders to the Exchange as well as to participate in the Exchange's new BAM process in an effort to qualify for the enhanced rebate or lower fee made available by the tiers.

The Exchange believes that the proposed tiers are reasonable, fair and

equitable, and non-discriminatory, for the reasons set forth above with respect to volume-based pricing generally and because such changes will incentivize participants to further contribute to market quality. The proposed tiers will provide an additional way for market participants to qualify for enhanced rebates or reduced fees. Further, BAM is fully available to all Members, and the proposed threshold is intentionally low to encourage Members to do the development work necessary to participate in BAM and send BAM Agency Orders.

#### Designated Give Up

In connection with the adoption of fees applicable to BAM, the Exchange proposes to add new fee code BC to the lead-in sentence of footnote 5 and to append footnote 5 to fee code BC in the Fee Codes and Associated Fees table of the Fee Schedule. In addition, the Exchange proposes to include reference to Routing Firms (*i.e.*, a Member who routed an order to the Exchange with a Designated Give up) in the proposed BAM Break-Up Credit section of footnote 6, to make clear that a Routing Firm too will be provided any applicable BAM Break-Up Credits. The Exchange believes this proposal is a reasonable and equitable allocation of fees and dues and is not unreasonably discriminatory because, as is currently the case pursuant to footnote 5, the proposal simply will make clear that a firm acting as a Routing Firm that routes BAM Agency Orders to the Exchange will be provided applicable rebates, including any BAM Break-Up Credits, based on the Routing Firm's decision to route the order to the Exchange.

#### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed rebate would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rebate represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Rather, the Exchange believes the proposal will enhance competition as it is a competitive proposal that seeks to further the growth of the Exchange by encouraging Members to enter BAM Agency Orders, orders in response to BAM Agency Orders, and orders to the Exchange generally.

The Exchange's proposal to adopt BAM was a competitive response to similar price improvement auctions operated by other options exchanges.

<sup>29</sup> See MIAX Fee Schedule; and Securities Exchange Act Release No. 72943 (August 28, 2014), 80 FR 52785 (September 4, 2014) (SR-MIAX-2015-45) (notice of filing and immediate effectiveness regarding MIAX PRIME). See also, *e.g.*, NYSE Amex Options Fee Schedule and NASDAQ BX Options Fee Schedule.

The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges. The Exchange anticipates that BAM will create new opportunities for EDGX to attract new business and compete on equal footing with those options exchanges with auctions. While the proposed fees and rebates are intentionally aggressive in order to attract participation on the Exchange, particularly in BAM, the Exchange does not believe that its proposed pricing significantly departs from pricing in place on other options exchanges that operate price improvement auctions. Accordingly, the Exchange does not believe that the proposal creates an undue burden on inter-market competition.

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe that its proposal to establish fees and rebates for BAM will impose any burden on competition, as discussed below.

The Exchange operates in a highly competitive market in which many sophisticated and knowledgeable market participants can readily and do send order flow to competing exchanges if they deem fee levels or rebate incentives at a particular exchange to be excessive or inadequate. Additionally, new competitors have entered the market and still others are reportedly entering the market shortly. These market forces ensure that the Exchange's fees and rebates remain competitive with the fee structures at other trading platforms. In that sense, the Exchange's proposal is actually pro-competitive because the Exchange is simply establishing rebates and fees in order to remain competitive in the current environment.

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the

Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed charges assessed and credits available to member firms in respect of BAM do not impose a burden on competition because the Exchange's execution and routing services are completely voluntary and subject to extensive competition. If the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result and/or will be unable to attract participants to BAM. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Additionally, the changes proposed herein are pro-competitive to the extent that they allow the Exchange to promote and maintain BAM, which has the potential to result in more efficient, price improved executions to the benefit of market participants.

The Exchange believes that the proposed change would increase both inter-market and intra-market competition by incentivizing members to direct their orders, and particularly Customer orders, to the Exchange, which benefits all market participants by providing more trading opportunities, which attracts market makers. To the extent that there is a differentiation between proposed fees assessed and rebates offered to Customers as opposed to other market participants, the Exchange believes that this is appropriate because the fees and rebates should incentivize members to direct additional order flow to the Exchange and thus provide additional liquidity that enhances the quality of its markets and increases the volume of contracts traded on the Exchange.

To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in order flow directed to the Exchange will benefit all market participants and improve competition on the Exchange. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive.

The Exchange believes that the proposed fees and rebates for participation in the BAM Auction are

not going to have an impact on intra-market competition based on the total cost for participants to transact as respondents to the Auction as compared to the cost for participants to engage in non-Auction electronic transactions on the Exchange.

As noted above, the Exchange believes that the proposed pricing for the BAM Auction is comparable to that of other exchanges offering similar electronic price improvement mechanisms, and the Exchange believes that, based on general industry experience, market participants understand that the price-improving benefits offered by an Auction justify and offset the transaction costs associated with such Auction. To the extent that there is a difference between non-BAM transactions and BAM transactions, the Exchange does not believe this difference will cause participants to refrain from responding to BAM or submitting orders to the Exchange when a BAM Auction is underway.

In addition, the Exchange does not believe that the proposed transaction fees and credits burden competition by creating a disparity of transaction fees between the BAM Contra Order and the transaction fees a Responder pays would result in certain participants being unable to compete with the contra side order.

The Exchange expects to see robust competition within the BAM Auction. As discussed, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange believes that the proposed rule change reflects this competitive environment because it establishes a fee structure in a manner that encourages market participants to direct their order flow, to provide liquidity, and to attract additional transaction volume to the Exchange.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>30</sup> and paragraph (f) of Rule 19b-4 thereunder.<sup>31</sup> At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-BatsEDGX-2017-01 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-BatsEDGX-2017-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for

inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BatsEDGX-2017-01, and should be submitted on or before February 7, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>32</sup>

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2017-00782 Filed 1-13-17; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79770; File No. SR-NASDAQ-2016-173]

### Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Reduce the All-Inclusive Annual Listing Fee for Limited Partnerships Listed on Nasdaq

January 10, 2017

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that, on December 28, 2016, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to reduce the fees for limited partnerships listed on Nasdaq.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on January 1, 2017.

A notice of the proposed rule change for publication in the **Federal Register** is attached as *Exhibit 1* [sic]. The text of the proposed rule change is set forth

below. Proposed new language is italicized; deleted text is in brackets.

\* \* \* \* \*

#### 5910. The Nasdaq Global Market (including the Nasdaq Global Select Market)

\* \* \* \* \*

##### IM-5910-1. All-Inclusive Annual Listing Fee

(a)-(c) No change.

(d) The All-Inclusive Annual Listing Fee will be calculated on total shares outstanding according to the following schedules:

(1)-(3) No change.

(4) Limited Partnerships (effective January 1, 2017):

Up to 75 million shares \$37,500  
75+ to 100 million shares \$50,000  
100+ to 125 million shares \$62,500  
125+ to 150 million shares \$67,500  
Over 150 million shares \$77,500

(e) No change.

\* \* \* \* \*

#### 5920. The Nasdaq Capital Market

\* \* \* \* \*

IM-5920-1. All-Inclusive Annual Listing Fee

(a)-(c) No change.

(d) The All-Inclusive Annual Listing Fee will be calculated on total shares outstanding according to the following schedules:

(1)-(3) No change.

(4) Limited Partnerships (effective January 1, 2017):

Up to 50 million shares \$30,000  
Over 50 million shares \$37,500

(e) No change.

\* \* \* \* \*

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

Nasdaq proposes to reduce the fees for limited partnerships listed on Nasdaq.

<sup>30</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>31</sup> 17 CFR 240.19b-4(f).

<sup>32</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

Historically, certain of Nasdaq's corporate governance requirements, including most shareholder approval requirements (other than for equity compensation), most independence requirements (other than for audit committees at the general partner level), and the annual meeting requirement (unless required by statute or regulation in the state in which the limited partnership is formed or doing business or by the terms of the partnership's limited partnership agreement), have not been applied to limited partnerships because their structure typically requires that public investors have limited rights and that the general partners make all significant decisions about the operation of the company.<sup>3</sup> As such, limited partners do not expect to have a voice in the operations of the partnership. Reduced corporate governance requirements for limited partnerships, in turn, result in Nasdaq expending fewer resources on monitoring and enforcing its rules because a significant portion of the regulatory cost Nasdaq incurs in connection with the continued listing of an issuer relates to the review by Nasdaq staff of complex transactions for compliance with Nasdaq's shareholder approval requirements, which limited partnerships are not subject to. Similarly, Nasdaq incurs lower regulatory costs in connection with the review by Nasdaq staff of limited partnerships' filings with the Commission because these issuers are not subject to most board and committee independence requirements (other than for audit committees at the general partner level), and most limited partnerships neither hold annual meetings nor file proxy statements. Accordingly, Nasdaq proposes to reduce the All-Inclusive Annual Listing Fee for limited partnerships listed on Nasdaq.

The proposed amendment will affect the All-Inclusive Annual Listing Fee schedule<sup>4</sup> on the Nasdaq Global Market, the Nasdaq Global Select Market, and the Nasdaq Capital Market.<sup>5</sup> In 2014, when Nasdaq adopted the All-Inclusive Annual Listing Fee schedule, Nasdaq considered various factors that distinguish companies, including

market tier, shares outstanding, and security type, as well as the perceived use of various Nasdaq regulatory and support services by companies of various characteristics.<sup>6</sup> Due to the relatively few limited partnerships listed on the Exchange at that time, Nasdaq's analysis did not focus on the special characteristics of the limited partnerships. Upon further consideration, Nasdaq now believes that the reduced regulatory oversight needed for limited partnerships warrants a reduced fee.

As detailed in the proposed rule, for limited partnerships listed on the Capital Market the All-Inclusive Annual Listing Fee will range from \$30,000 to \$37,500. On the Global and Global Select Markets, the All-Inclusive Annual Listing Fee for limited partnerships will range from \$37,500 to \$77,500.<sup>7</sup> The proposed fees will continue to be based on a limited partnership's total shares outstanding and will maintain the same pricing tiers based on shares outstanding as in the current fee schedule applicable to limited partnerships, except the tiers that otherwise would have their fees reduced below the minimum fee of \$37,500 for the Global and Global Select Markets or \$30,000 for the Capital Market are combined into a single pricing tier of up to 75 million shares outstanding on the Global and Global Select Markets and of up to 50 million shares outstanding on the Capital Market.

Nasdaq notes that American Depositary Receipts (ADRs) and Closed-end Funds also have different fee schedules than other listed equity securities. Nasdaq believes that the characteristics of ADRs and Closed-end Funds are different than the characteristics of limited partnerships and that it is therefore appropriate to apply a different fee schedule for limited partnerships.<sup>8</sup>

<sup>6</sup> See Securities Exchange Act Release No. 73647, *supra* note 4.

<sup>7</sup> The proposed fees are generally 50% less than the fees applicable to issuers of equity securities other than ADRs and Closed-End Funds. However, Nasdaq maintained a minimum fee of \$37,500 for the Global and Global Select Markets and \$30,000 for the Capital Market in recognition of the regulatory work Nasdaq must nonetheless perform and the benefits a limited partnership accrues with listing, and in consideration of the minimum fees set by Nasdaq's competitors.

<sup>8</sup> See Securities Exchange Act Release No. 73647, *supra* note 4, noting, among other differences, that the U.S. listing is not typically the issuer of an ADR's primary listing, and that Closed-end Funds are particularly sensitive to the expenses they incur, given that they compete for investment dollars based on return, but are otherwise subject to the same regulatory requirements as other listed companies.

The proposed fee change will be operative January 1, 2017.

Nasdaq notes that no other company will be required to pay higher fees as a result of the proposed amendments and represents that the proposed fee change will have no impact on the resources available for its regulatory programs.

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>9</sup> in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,<sup>10</sup> in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As a preliminary matter, Nasdaq competes for listings with other national securities exchanges and companies can easily choose to list on, or transfer to, those alternative venues. As a result, the fees Nasdaq can charge listed companies are constrained by the fees charged by its competitors and Nasdaq cannot charge prices in a manner that would be unreasonable, inequitable, or unfairly discriminatory.

Nasdaq believes that the proposed fee change reducing the fee paid by limited partnerships is reasonable and not unfairly discriminatory because it recognizes the reduced regulatory cost Nasdaq incurs for limited partnerships. Specifically, certain of Nasdaq's corporate governance requirements, including most shareholder approval requirements (other than for equity compensation), most independence requirements (other than for audit committees at the general partner level), and the annual meeting requirement (unless required by statute or regulation in the state in which the limited partnership is formed or doing business or by the terms of the partnership's limited partnership agreement), do not apply to limited partnerships because their structure typically requires that public investors have limited rights and that the general partners make all significant decisions about the operation of the company. This allows Nasdaq to expend fewer resources on monitoring and enforcing its rules because a significant portion of the regulatory cost Nasdaq incurs in connection with the continued listing of an issuer relates to the review by Nasdaq staff of complex transactions for compliance with

<sup>9</sup> 15 U.S.C. 78f(b).

<sup>10</sup> 15 U.S.C. 78f(b)(4) and (5).

<sup>3</sup> See Rule 5615(a)(4).

<sup>4</sup> In 2014, Nasdaq adopted an All-Inclusive Annual Listing Fee schedule. Securities Exchange Act Release No. 73647 (November 19, 2014), 79 FR 70232 (November 25, 2014) (SR-NASDAQ-2014-87). All newly listed companies are subject to the All-Inclusive fee structure and other listed companies can elect to be on the All-Inclusive fee structure. All companies will be subject to the All-Inclusive fee structure effective January 1, 2018.

<sup>5</sup> Listing Rule 5910 provides that fee schedules for the Nasdaq Global Select Market are the same fee schedules as for the Nasdaq Global Market.

Nasdaq's shareholder approval requirements, which limited partnerships are not subject to. Similarly, Nasdaq incurs lower regulatory costs in connection with the review by Nasdaq staff of limited partnerships' filings with the Commission because these issuers are not subject to most board and committee independence requirements (other than for audit committees at the general partner level), and most limited partnerships neither hold annual meetings nor file proxy statements. These reduced costs are a non-discriminatory reason to charge limited partnerships a lower All-Inclusive Annual Listing Fee.

Currently, ADRs and Closed-end Funds also pay lower All-Inclusive Annual Listing Fees than other issuers of equity securities. Nasdaq believes it is appropriate to apply a fee schedule to limited partnerships that is different from those applicable to either ADRs or Closed-end Funds due to their differing characteristics. Specifically, Nasdaq charges lower listing fees for ADRs because, among other differences, the U.S. listing is not typically the issuer of an ADR's primary listing.<sup>11</sup> Similarly, Nasdaq charges lower listing fees for Closed-end Funds because they are particularly sensitive to the expenses they incur, given that they compete for investment dollars based on return.<sup>12</sup> As a result, offering a different discount to limited partnerships on the All-Inclusive Annual Fee schedule than to ADRs and Closed-end Funds is not inequitable or unfairly discriminatory.

While the proposed fee reduction only applies to limited partnerships on the All-Inclusive Annual Fee schedule, Nasdaq notes that any currently listed limited partnership can opt into the All-Inclusive Annual Fee schedule for 2017 prior to December 31, 2016, and that all companies will transition to that fee schedule in 2018. Moreover, Nasdaq accrues benefits from companies being on this schedule.<sup>13</sup> These benefits to Nasdaq provide a reasonable basis for Nasdaq to adjust the fees only for limited partnerships on the All-Inclusive Annual Fee schedule and, as a result, offering a discount only to limited partnerships on the All-Inclusive Fee schedule is not inequitable or unfairly discriminatory.

<sup>11</sup> See Securities Exchange Act Release No. 73647, *supra* note 4.

<sup>12</sup> *Id.*

<sup>13</sup> These benefits include eliminating the multiple invoices otherwise sent to a company each year and providing more certainty as to Nasdaq's revenues. See Securities Exchange Act Release No. 73647, *supra* note 4.

Finally, Nasdaq believes that the proposed fees are consistent with the investor protection objectives of Section 6(b)(5) of the Act<sup>14</sup> in that they are designed to promote just and equitable principles of trade, to remove impediments to a free and open market and national market system, and in general to protect investors and the public interest. Specifically, the amount of revenue forgone by allowing limited partnerships to pay lower fees is not substantial, and the reduced fees may result in more limited partnerships listing on Nasdaq, thereby increasing the resources available for Nasdaq's listing compliance program, which helps to assure that listing standards are properly enforced and investors are protected. Consequently, Nasdaq believes that the potential loss of revenue from the reduction of fees payable by limited partnerships, as proposed, will not hinder its ability to fulfill its regulatory responsibilities.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The market for listing services is extremely competitive and listed companies may freely choose alternative venues based on the aggregate fees assessed, and the value provided by each listing. This rule proposal does not burden competition with other listing venues, which are similarly free to set their fees. For these reasons, Nasdaq does not believe that the proposed rule change will result in any burden on competition for listings.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.<sup>15</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection

of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NASDAQ-2016-173 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2016-173. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2016-173, and should be submitted on or before February 7, 2017.

<sup>14</sup> 15 U.S.C. 78f(b)(5).

<sup>15</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>16</sup>

**Eduardo A. Aleman,**

*Assistant Secretary,*

[FR Doc. 2017-00783 Filed 1-13-17; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79767; File No. SR-NYSEArca-2016-62]

### Self-Regulatory Organizations; NYSEArca, Inc.; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Relating to a Change to the Underlying Index for the PowerShares Build America Bond Portfolio

January 10, 2017.

#### I. Introduction

On May 3, 2016, NYSE Arca, Inc. (“NYSE Arca” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to: (1) Propose changes to the index underlying the PowerShares Build America Bond Portfolio (“Fund”) and the name of the Fund and (2) permit the continued listing and trading of the shares (“Shares”) of the Fund as a result of the changes to the index underlying the Fund. The proposed rule change was published for comment in the **Federal Register** on May 23, 2016.<sup>3</sup>

On June 27, 2016, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> On August 12, 2016, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.<sup>6</sup> On October 27, 2016, the Commission issued a notice of designation of a longer period for Commission action on proceedings to determine whether to approve or

disapprove the proposed rule change.<sup>7</sup> On January 4, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>8</sup> The Commission has received no comments on the proposed rule change. This order grants approval of the proposed rule change, as modified by Amendment No. 1 thereto.

#### II. Exchange’s Description of the Proposal

The Exchange currently lists and trades Shares of the Fund<sup>9</sup> under NYSE Arca Equities Rule 5.2(j)(3), Commentary .02, which governs the listing and trading of Investment Company Units (“Units”) based on fixed income securities indexes.<sup>10</sup> The Fund is a series of the Trust. Invesco PowerShares Capital Management LLC is the investment adviser (“Adviser”) for the Fund. Invesco Distributors, Inc. is the Fund’s distributor. The Bank of New York Mellon is the administrator, custodian, and fund accounting and transfer agent for the Fund.

The Fund currently seeks investment results that generally correspond to the price and yield (before fees and expenses) of The Bank of America

<sup>7</sup> See Securities Exchange Act Release No. 79173, 81 FR 76400 (Nov. 2, 2016). The Commission designated January 18, 2017 as the date by which it should approve or disapprove the proposed rule change.

<sup>8</sup> In Amendment No. 1 to the proposed rule change, the Exchange: (a) Clarified that (i) in no event will the New Index (as defined herein) be composed of fewer than 500 issues, and (ii) FINRA (as defined herein) is able to access data obtained from the Municipal Securities Rulemaking Board relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares; (b) stated that that Adviser (as defined herein) represents that within a single municipal bond issuer, separate issues by the same issuer are likely to trade similarly to one another, and that individual CUSIPs within the New Index that share characteristics with other CUSIPs have a high yield to maturity correlation, and frequently have a correlation of one or close to one; and (c) made other technical edits and non-substantive corrections. Because Amendment No. 1 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 1 is not subject to notice and comment. Amendment No. 1, which amended and replaced the original filing in its entirety, is available on the Commission’s Web site at: <https://www.sec.gov/comments/sr-nysearca-2016-62/nysearca201662-1460311-130254.pdf>.

<sup>9</sup> The Exchange states that, on February 26, 2016, PowerShares Exchange-Traded Fund Trust II (“Trust”) filed a post-effective amendment on Form 485 under the Securities Act of 1933 (“Securities Act”) to its registration statement on Form N-1A under the Securities Act and the Investment Company Act of 1940 (“1940 Act”) (File Nos. 333-138490 and 811-21977) (“Registration Statement”). The Exchange states that the Trust has obtained certain exemptive relief under the 1940 Act (File No. 812-13335) (“Exemptive Order”).

<sup>10</sup> The Exchange states that the PowerShares Build America Bond Portfolio was initially listed on November 17, 2009 pursuant to the generic listing criteria of Commentary .02 to NYSE Arca Equities Rule 5.2(j)(3).

(“BofA”) Merrill Lynch Build America Bond Index (“Build America Bond Index”). The Fund generally invests at least 80% of its total assets in taxable municipal securities eligible to participate in the Build America Bond program created under the American Recovery and Reinvestment Act of 2009 or other legislation providing for the issuance of taxable municipal securities on which the issuer receives federal support of the interest paid (“Build America Bonds”) and that comprise the Build America Bond Index. The Build America Bond Index is designed to track the performance of U.S. dollar-denominated investment grade taxable municipal debt publicly issued under the Build America Bond program by U.S. states and territories, and their political subdivisions, in the U.S. market. Qualifying securities must have a minimum amount outstanding of \$1 million, at least 18 months remaining term to final maturity at the time of issuance, at least one year remaining term to final maturity, a fixed coupon schedule, and an investment grade rating (based on an average of Moody’s Investors Services, Inc. (“Moody’s”), Standard & Poor’s, a division of The McGraw-Hill Company, Inc. (“S&P”), and Fitch Ratings, Inc. (“Fitch”).

The Trust has proposed to change the index underlying the Fund to the BofA Merrill Lynch US Taxable Municipal Securities Plus Index (“New Index”) and to change the name of the Fund to PowerShares Taxable Municipal Bond Portfolio. The Exchange represents that the New Index does not meet the generic listing criteria of NYSE Arca Equities Rule 5.2(j)(3). The Exchange submitted this proposed rule change to permit the continued listing of the Fund. The New Index meets all of the requirements of the generic listing criteria of NYSE Arca Equities Rule 5.2(j)(3), except for that set forth in Commentary .02(a)(2).<sup>11</sup> Specifically, as of February 4, 2016, approximately 60.51% of the New Index weight was composed of individual maturities of \$100 million or more (determined at the time of issuance).

#### A. Changes to the Index Underlying the Fund

According to the Exchange, the Fund currently has a non-fundamental policy to invest at least 80% of its net assets (plus the amount of any borrowings for investment purposes) in Build America

<sup>11</sup> Commentary .02(a)(2) to NYSE Arca Equities Rule 5.2(j)(3) provides that components that in the aggregate account for at least 75% of the weight of the index or portfolio each shall have a minimum original principal amount outstanding of \$100 million or more.

<sup>16</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 77849 (May 17, 2016), 81 FR 32371 (“Notice”).

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 78157, 81 FR 43327 (July 1, 2016).

<sup>6</sup> See Securities Exchange Act Release No. 78564, 81 FR 55247 (Aug. 18, 2016).

Bonds. Moreover, as stated in the Registration Statement, the Fund complies with that non-fundamental policy because it also is required generally to invest at least 80% of the value of its total assets in the Build America Bonds that comprise the Build America Bond Index, in accordance with the terms of the relief set forth in the Trust's Exemptive Order.

However, in response to a changing market environment that includes a reduction in the number of Build America Bonds, the Adviser has proposed that the Fund's underlying index be changed from one that is focused on Build America Bonds to one that is more broadly focused on taxable municipal debt in general, and which may include Build America Bonds. Changing the Fund's underlying index would require changing the non-fundamental policy set forth above. Accordingly, before the Fund can change its underlying index, the Registration Statement states that the Fund's board of trustees ("Board") must approve the underlying index change, and the Fund must provide shareholders with sixty days written notice of the change.

Thus, after this proposed rule change is approved, the Trust represents that it intends to seek to obtain Board approval and provide the requisite shareholder notice. Subject to that Board approval and shareholder notice, the Fund intends to change its underlying index to one that is composed of taxable municipal securities, including both Build America Bonds and non-Build America Bonds. Following such change, the proposed underlying index for the Fund will be the New Index.

According to the Exchange, the change in the Fund's underlying index is designed to enable the Fund to expand its range of investments in light of a diminishing supply of Build America Bonds; otherwise, there is no other change to the Fund's investment strategies or objective. After such change, the Fund's investment objective will be to seek investment results that generally correspond (before fees and expenses) to the price and yield of the New Index. The Fund's new non-fundamental investment policy will be to invest at least 80% of its net assets (plus borrowings for investment purposes) in taxable municipal securities. In addition, the Fund generally will invest at least 80% of its total assets in the securities that will compose the New Index, in accordance with the terms of the Trust's Exemptive Order. However, the Fund may invest up to 20% of its total assets in securities not included in the New Index, money

market instruments, including repurchase agreements or other funds that invest exclusively in money market instruments (subject to applicable limitations under the 1940 Act or exemptions therefrom), convertible securities and structured notes (notes on which the amount of principal repayment and interest payments is based on the movement of one or more specified factors, such as the movement of a particular security or securities index), all to the extent that the Adviser believes investment in such instruments will facilitate the Fund's ability to achieve its new investment objective. In addition, the Fund intends to change its name to "PowerShares Taxable Municipal Bond Portfolio."<sup>12</sup>

#### B. Description of the New Index<sup>13</sup>

The New Index tracks the performance of U.S. dollar denominated taxable municipal debt publicly issued by U.S. states and territories, and their political subdivisions, in the U.S. domestic market. Qualifying securities must be subject to U.S. federal taxes and must have at least 18 months to maturity at point of issuance, at least one year remaining term to final maturity, a fixed coupon schedule (including zero coupon bonds), and an investment grade rating (based on an average of Moody's, S&P, and Fitch). The call date on which a pre-refunded bond will be redeemed is used for purposes of determining qualification with respect to final maturity requirements. For Build America Bonds to qualify for inclusion, the securities must have a minimum amount outstanding of \$1 million and be only "direct pay" (*i.e.*, a direct federal subsidy is paid to the issuer); "tax-credit" (*i.e.*, where the investor receives a tax credit on the interest payments) Build America Bonds are excluded. For all other securities, minimum size requirements vary based on the initial

<sup>12</sup> The Exchange represents that the changes described herein with respect to use of the New Index will be effective upon: (1) Approval by the Trust's Board; (2) shareholders' receipt of sixty days written notice of the proposed change; and (3) completing a filing with the Commission of another amendment to the Trust's Registration Statement, or a prospectus supplement reflecting these changes. According to the Exchange, the Adviser has managed and will continue to manage the Fund in the manner described in the Registration Statement and will not implement the changes described herein until this proposed rule change is operative.

<sup>13</sup> The Exchange states that the description of the New Index is based on information provided by BofA Merrill Lynch, which is the "Index Provider" with respect to the Underlying Index and the New Index. The Index Provider is a broker-dealer and has implemented a firewall with respect to, and will maintain procedures designed to prevent the use and dissemination of material non-public information regarding, the New Index.

term to final maturity at time of issuance. Securities with an initial term to final maturity greater than or equal to one year and less than five years must have a current amount outstanding of at least \$10 million. Securities with an initial term to final maturity greater than or equal to five years and less than ten years must have a current amount outstanding of at least \$15 million. Securities with an initial term to final maturity of ten years or more must have a current amount outstanding of at least \$25 million. Local bonds issued by U.S. territories within their jurisdictions that are tax exempt within the U.S. territory but not elsewhere are excluded from the New Index. All Rule 144A securities, both with and without registration rights, and securities in legal default are excluded from the New Index. New Index constituents are capitalization-weighted based on their current amount outstanding times the market price plus accrued interest. Accrued interest is calculated assuming next-day settlement. Cash flows from bond payments that are received during the month are retained in the New Index until the end of the month and then are removed as part of the rebalancing. Cash does not earn any reinvestment income while it is held in the New Index.<sup>14</sup> The New Index is rebalanced on the last calendar day of the month, based on information available up to and including the third business day before the last business day of the month. No changes are made to constituent holdings other than on month end rebalancing dates.

As of February 4, 2016, approximately 84.39% of the weight of the New Index components was composed of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding of \$100 million or more for all maturities of the offering. In addition, as of February 4, 2016, the total dollar amount outstanding of issues in the New Index was approximately \$281,589,346,769, and the average dollar amount outstanding of issues in the New Index was approximately \$ 27,808,547. Further, the most heavily weighted component represents 2.27% of the weight of the New Index, and the five most heavily weighted components represent 6.33% of the weight of the New Index.<sup>15</sup> The

<sup>14</sup> Information concerning constituent bond prices, timing, and conventions is provided in the BofA Merrill Lynch Bond Index Guide, which can be accessed on Bloomberg.

<sup>15</sup> Commentary .02(a)(4) to NYSE Arca Equities Rule 5.2(j)(3) provides that no component fixed-income security (excluding Treasury Securities and



Exchange also states that the New Index is composed of approximately 10,126 issues and 1,811 unique issuers, and that in no event will the New Index be composed of fewer than 500 issues. According to the proposal, within a single municipal bond issuer, separate issues by the same issuer are likely to trade similarly to one another, and individual CUSIPs within the New Index that share characteristics with other CUSIPs have a high yield to maturity correlation, and frequently have a correlation of one or close to one. All components of the New Index have at least an investment grade composite rating of BBB3 or higher (based on an average of S&P, Moody's, and Fitch).

The Exchange represents that: (1) With respect to the New Index, except for Commentary .02(a)(2) to NYSE Arca Equities Rule 5.2(j)(3), the Shares of the New Index currently satisfy all of the generic listing standards under NYSE Arca Equities Rule 5.2(j)(3); (2) the continued listing standards under NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) applicable to Units shall apply to the Shares of the Fund; and (3) the Trust is required to comply with Rule 10A-3 under the Act<sup>16</sup> for the initial and continued listing of the Shares of the Fund. In addition, the Exchange represents that the Shares of the Fund will comply with all other requirements applicable to Units including, but not limited to, requirements relating to the dissemination of key information such as the value of the New Index and the applicable Intraday Indicative Value ("IIV"),<sup>17</sup> rules governing the trading of equity securities, trading hours, trading halts, surveillance, information barriers, and the Information Bulletin to Equity Trading Permit Holders ("ETP Holders"), as set forth in Exchange rules applicable to Units and prior Commission orders approving the generic listing rules applicable to the listing and trading of Units.<sup>18</sup>

GSE Securities, as defined therein) shall represent more than 30% of the weight of the index or portfolio, and the five most heavily weighted component fixed-income securities in the index or portfolio shall not in the aggregate account for more than 65% of the weight of the index or portfolio.

<sup>16</sup> 17 CFR 240.10A-3.

<sup>17</sup> The IIV will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session of 9:30 a.m. to 4:00 p.m., Eastern time. According to the Exchange, several major market data vendors display and/or make widely available IIVs taken from the Consolidated Tape Association ("CTA") or other data feeds.

<sup>18</sup> See, e.g., Securities Exchange Act Release Nos. 55783 (May 17, 2007), 72 FR 29194 (May 24, 2007) (SR-NYSEArca-2007-36) (order approving NYSE Arca generic listing standards for Units based on a fixed income index); 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR-PCX-2001-14) (order

### III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act<sup>19</sup> and the rules and regulations thereunder applicable to a national securities exchange.<sup>20</sup> In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,<sup>21</sup> which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,<sup>22</sup> which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. The current value of the New Index is widely disseminated by one or more major market data vendors at least once per day, as required by NYSE Arca Equities Rule 5.2(j)(3), Commentary .02(b)(ii). In addition, the IIV for the Shares of the Fund is disseminated by one or more major market data vendors and is updated at least every 15 seconds during the Exchange's Core Trading Session, as required by NYSE Arca Equities Rule 5.2(j)(3), Commentary .02(c). The components and percentage weightings of the New Index are available from major market data vendors, and the portfolio of securities held by the Fund is disclosed daily on the Fund's Web site. The Exchange also represents that information regarding market price and trading volume of the

approving generic listing standards for Units and Portfolio Depositary Receipts); 41983 (October 6, 1999), 64 FR 56008 (October 15, 1999) (SR-PCX-98-29) (order approving rules for listing and trading of Units).

<sup>19</sup> 15 U.S.C. 78f.

<sup>20</sup> In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>21</sup> 17 U.S.C. 78f(b)(5).

<sup>22</sup> 15 U.S.C. 78k-1(a)(1)(C)(iii).

Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last-sale information will be available via the CTA high-speed line. Moreover, trade price and other information relating to municipal bonds are available through the Municipal Securities Rulemaking Board's Electronic Municipal Market Access ("EMMA") system. The Web site for the Fund will include the prospectus for the Fund and additional data relating to net asset value ("NAV") and other applicable quantitative information.

The Commission believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. If the Exchange becomes aware that the NAV is not being disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. If the IIV and the New Index value are not being disseminated as required, the Exchange may halt trading during the day in which the interruption to the dissemination of the IIV or New Index value occurs. If the interruption to the dissemination of the IIV or New Index value persists past the trading day in which it occurred, the Exchange will halt trading. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Equities Rule 7.34, which sets forth circumstances under which Shares of the Fund may be halted.<sup>23</sup> The Exchange states that trade price and other information relating to municipal bonds is available through the Municipal Securities Rulemaking Board's Electronic Municipal Market Access system.

Based on the Exchange's representations, the Commission believes that the New Index is

<sup>23</sup> With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.

sufficiently broad-based to deter potential manipulation. The Exchange represents that, as of February 4, 2016, approximately 84.39% of the weight of the New Index components was composed of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding of \$100 million or more for all maturities of the offering. In addition, as of February 4, 2016, the total dollar amount outstanding of issues in the New Index was approximately \$281,589,346,769, and the average dollar amount outstanding of issues in the Index was approximately \$ 27,808,547. Further, the most heavily weighted component represented 2.27% of the weight of the New Index, and the five most heavily weighted components represented 6.33% of the weight of the New Index.<sup>24</sup> The Exchange also represents that the New Index is composed of approximately 10,126 issues and 1,811 unique issuers, and that in no event will the New Index be composed of fewer than 500 issues.

In support of this proposal, the Exchange has also made representations, including:

(1) The Adviser has managed and will continue to manage the Fund in the manner described in the Registration Statement, and it will not implement the changes described herein until this proposed rule change is operative.

(2) The Index Provider is a broker-dealer and has implemented a firewall with respect to, and will maintain procedures designed to prevent the use and dissemination of material, non-public information regarding, the New Index.

(3) With respect to the New Index, except for Commentary .02(a)(2) to NYSE Arca Equities Rule 5.2(j)(3), the Shares of Fund overlying the New Index would satisfy all of the current generic listing standards under NYSE Arca Equities Rule 5.2(j)(3).

(4) The continued listing standards under NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) applicable to Units shall apply to the Shares of the Fund overlying the New Index.

(5) The Trust is required to comply with Rule 10A-3 under the Act<sup>25</sup> for the initial and continued listing of the Shares of the Fund overlying the New Index.

(6) The Shares of the Fund overlying the New Index will comply with all other requirements applicable to Units including, but not limited to, requirements relating to the

dissemination of key information such as the value of the New Index and the applicable IIV,<sup>26</sup> rules governing the trading of equity securities, trading hours, trading halts, surveillance, information barriers, and the Information Bulletin to ETP Holders, as set forth in Exchange rules applicable to Units and prior Commission orders approving the generic listing rules applicable to the listing and trading of Units.<sup>27</sup>

(7) The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (“FINRA”) on behalf of the Exchange, which are designed to detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.<sup>28</sup> The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

(8) The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the Intermarket Surveillance Group (“ISG”). In addition, the Exchange will communicate as needed regarding trading in the Shares with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. FINRA also can access data obtained from the Municipal Securities Rulemaking Board relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares.

The Exchange represents that all statements and representations made in this proposal regarding (a) the description of the Fund’s portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange. The Adviser has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and,

pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements.<sup>29</sup> If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5(m). This approval order is based on all of the Exchange’s representations, including those set forth above and in the Notice, as modified by Amendment No. 1 thereto, and the Exchange’s description of the Funds.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1 thereto, is consistent with Section 6(b)(5) of the Act<sup>30</sup> and the rules and regulations thereunder applicable to a national securities exchange.

#### IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>31</sup> that the proposed rule change (SR–NYSEArca–2016–62), as modified by Amendment No. 1 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>32</sup>

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2017–00780 Filed 1–13–17; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>24</sup> See *supra* note 15.

<sup>25</sup> 17 CFR 240.10A-3.

<sup>26</sup> See *supra* note 17.

<sup>27</sup> See *supra* note 18 and accompanying text.

<sup>28</sup> The Exchange represents that FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA’s performance under this regulatory services agreement.

<sup>29</sup> The Commission notes that certain other proposals for the listing and trading of Managed Fund Shares include a representation that the exchange will “surveil” for compliance with the continued listing requirements. See, e.g., Securities Exchange Act Release No. 78005 (Jun. 7, 2016), 81 FR 38247 (Jun. 13, 2016) (SR–BATS–2015–100). In the context of this representation, it is the Commission’s view that “monitor” and “surveil” both mean ongoing oversight of a fund’s compliance with the continued listing requirements. Therefore, the Commission does not view “monitor” as a more or less stringent obligation than “surveil” with respect to the continued listing requirements.

<sup>30</sup> 15 U.S.C. 78f(b)(5).

<sup>31</sup> 15 U.S.C. 78s(b)(2).

<sup>32</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79766; File No. SR-BatsBZX-2016-92]

### Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Amending Fees To Adopt a New Cross-Asset Step-Up Tier

January 10, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 30, 2016, Bats BZX Exchange, Inc. (the “Exchange” or “BZX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act<sup>3</sup> and Rule 19b-4(f)(2) thereunder,<sup>4</sup> which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members<sup>5</sup> and non-members of the Exchange pursuant to BZX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange’s Web site at [www.bats.com](http://www.bats.com), at the principal office of the Exchange, and at the Commission’s Public Reference Room.

#### II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

#### (A) Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange is proposing to adopt a new Tier 4 under footnote 3, Cross-Asset Step-Up Tiers and to rename the existing Tier 4 as Tier 5. Currently, with respect to the Exchange’s equities trading platform (“BZX Equities”), the Exchange determines the fee charged for the removal of liquidity or the rebate for adding liquidity that it will provide to Members using the Exchange’s tiered pricing structure, which is based on the Member meeting certain volume tiers based on their ADAV<sup>6</sup> as a percentage of TCv<sup>7</sup> or ADV<sup>8</sup> as a percentage of TCv. Included amongst the volume tiers offered on BZX Equities are four Cross-Asset Step-Up Tiers, which require participation on the Exchange’s equity options platform (“BZX Options”). The current Cross-Asset Step-Up Tiers provide rebates of \$0.0027, \$0.0028 and \$0.0029 per share for Tier 1, Tier 2, and Tier 3, respectively, and charge a fee of \$0.00295 per share for the existing Tier 4. To qualify for Tier 1, a Member must have an Options Step-Up Add TCv<sup>9</sup> that is equal to or greater than 0.30%. To qualify for Tier 2, a Member must have an Options Step-Up Add TCv<sup>10</sup> that is equal to or greater than 0.40%. To qualify for Tier 3, a Member must have an Options Add TCv<sup>11</sup> greater than or equal to 0.30% and have a Step-Up ADAV from June 2015 greater than [sic] 1,000,000. The existing Tier 4 requires a Member to have an Options Customer Remove TCv<sup>12</sup> greater than or equal to 0.30% and a Step-Up Remove TCv<sup>13</sup> from July 2016 greater than or equal to 0.05%.

The Exchange now proposes to adopt a new tier, Tier 4, and to rename the existing Tier 4 as Tier 5. Under the proposed new Tier 4, the Exchange would provide a rebate of \$0.0032 per share to Members that have an Options

<sup>6</sup> As defined in the Exchange’s fee schedule available at [http://www.bats.com/us/equities/membership/fee\\_schedule/bzx/](http://www.bats.com/us/equities/membership/fee_schedule/bzx/).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> As defined in the Exchange’s fee schedule available at [http://www.bats.com/us/equities/membership/fee\\_schedule/bzx/](http://www.bats.com/us/equities/membership/fee_schedule/bzx/).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

Step-Up Add TCv in Customer<sup>14</sup> orders from October 2016 baseline greater than or equal to 0.35%. Other than renaming current Tier 4 as Tier 5, no additional changes are proposed for the renamed Tier 5.

#### Implementation Date

The Exchange proposes to implement these amendments to its fee schedule January 3, 2017.<sup>15</sup>

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,<sup>16</sup> in general, and furthers the objectives of Section 6(b)(4),<sup>17</sup> in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

Volume-based rebates such as the proposed Cross-Asset Step-Up Tier 4 have been widely adopted by equities and options exchanges and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange’s market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and introduction of higher volumes of orders into the price and volume discovery processes. The Exchange believes that the proposal to add a Cross-Asset Step-Up Tier 4 is a reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and rebates because it will provide

<sup>14</sup> As defined in the Exchange’s fee schedule available at [http://www.bats.com/us/equities/membership/fee\\_schedule/bzx/](http://www.bats.com/us/equities/membership/fee_schedule/bzx/).

<sup>15</sup> The Exchange notes that the date of its fee schedule was previously updated to January 3, 2017 in SR-BatsBZX-2016-87 (December 6, 2017 [sic]). See Securities Exchange Act Release No. 79636 (December 21, 2016).

<sup>16</sup> 15 U.S.C. 78f.

<sup>17</sup> 15 U.S.C. 78f(b)(4).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

<sup>4</sup> 17 CFR 240.19b-4(f)(2).

<sup>5</sup> The term “Member” is defined as “any registered broker or dealer that has been admitted to membership in the Exchange.” See Exchange Rule 1.5(n).

Members with an additional incentive to reach certain thresholds on both the BZX Equities and BZX Options. The increased liquidity from this proposal also benefits all investors by deepening the BZX Equities and BZX Options liquidity pools, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. Such pricing programs thereby reward a Member's growth pattern on the Exchange and such increased volume increases potential revenue to the Exchange, and will allow the Exchange to continue to provide and potentially expand the incentive programs operated by the Exchange. To the extent a Member participates on BZX Equities but not on BZX Options, the Exchange does believe that the proposal is still reasonable, equitably allocated and non-discriminatory with respect to such Member based on the overall benefit to the Exchange resulting from the success of BZX Options. As noted above, such success allows the Exchange to continue to provide and potentially expand its existing incentive programs to the benefit of all participants on the Exchange, whether they participate on BZX Options or not. The proposed pricing program is also fair and equitable in that membership in BZX Options is available to all market participants which would provide them with access to the benefits on BZX Options provided by the proposed changes, as described above, even where a Member of BZX Options is not necessarily eligible for the proposed increased rebates on the Exchange. Further, the proposed changes will result in Members receiving either the same or an increased rebate than they would currently receive.

Lastly, the Exchange believes the proposed tier's criteria and corresponding rebate are equitable and reasonable as compared to other Cross Asset Step-Up Tiers under footnote 3. For example, to qualify for Tier 3 and receive a rebate of \$0.0029 per share, a Member must have an Options Add TCV greater than or equal to 0.30% and have a Step-Up ADAV from June 2015 greater than [sic] 1,000,000. Under the proposed tier, a Member would receive a higher rebate of \$0.0032 per share where they satisfy more stringent criteria of having an Options Step-Up Add TCV in Customer orders from October 2016 baseline greater than or equal to 0.35%.

*(B) Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe its proposed amendment to its fee schedule would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee structures to be unreasonable or excessive. The proposed changes are generally intended to offer an incentive resulting in a rebate for adding liquidity on the Exchange, which is intended to draw additional participants to the Exchange. The Exchange does not believe that the proposed new Cross-Asset Step-Up Tier 4 would burden competition, but instead, enhance competition, as it is intended to increase the competitiveness of and draw additional volume to the Exchange. The Exchange does not believe the proposed amendments would burden intramarket competition as they would be available to all Members uniformly.

*(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>18</sup> and paragraph (f) of Rule 19b-4 thereunder.<sup>19</sup> At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-BatsBZX-2016-92 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BatsBZX-2016-92. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BatsBZX-2016-92 and should be submitted on or before February 7, 2017.

<sup>18</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>19</sup> 17 CFR 240.19b-4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>20</sup>

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2017-00779 Filed 1-13-17; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79768; File No. SR-BOX-2016-48]

### Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change To Adopt Rules for an Open-Outcry Trading Floor

January 10, 2017.

On November 16, 2016, BOX Options Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposal to adopt rules for an open-outcry trading floor. The proposed rule change was published for comment in the **Federal Register** on December 05, 2016.<sup>3</sup> The Commission received two comment letters on the proposed rule change.<sup>4</sup>

Section 19(b)(2) of the Act<sup>5</sup> provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is January 19, 2017.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time

to consider and take action on the Exchange's proposed rule change.

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act<sup>6</sup> and for the reasons stated above, the Commission designates March 5, 2017 as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-BOX-2016-48).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>7</sup>

**Eduardo A. Aleman,**  
*Assistant Secretary.*

[FR Doc. 2017-00781 Filed 1-13-17; 8:45 am]

BILLING CODE 8011-01-P

## DEPARTMENT OF STATE

[Public Notice 9855]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: "Alexei Jawlensky" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Alexei Jawlensky," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Neue Galerie, New York, New York, from on or about February 16, 2017, until on or about May 29, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-

632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**Mark Taplin,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2017-00749 Filed 1-13-17; 8:45 am]

BILLING CODE 4710-05-P

## DEPARTMENT OF STATE

[Public Notice 9856]

### Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: "Enlightened Princesses: Caroline, Augusta, Charlotte, and the Shaping of the Modern World" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Enlightened Princesses: Caroline, Augusta, Charlotte, and the Shaping of the Modern World," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Yale Center for British Art, New Haven, Connecticut, from on or about February 2, 2017, until on or about April 30, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: [section2459@state.gov](mailto:section2459@state.gov)). The mailing address is U.S.

<sup>20</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 79421 (November 29, 2016), 81 FR 87607.

<sup>4</sup> See letters to Brent J. Fields, Secretary, Commission, from Steve Crutchfield, Head of Market Structure, CTC Trading Group, LLC, dated December 31, 2016 and Joan C. Conley, Senior Vice President and Corporate Secretary, Nasdaq, dated December 22, 2016.

<sup>5</sup> 15 U.S.C. 78s(b)(2).

<sup>6</sup> 15 U.S.C. 78s(b)(2)(A)(ii)(I).

<sup>7</sup> 17 CFR 200.30-3(a)(31).

Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

**Mark Taplin,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2017-00769 Filed 1-13-17; 8:45 am]

**BILLING CODE 4710-05-P**

**DEPARTMENT OF STATE**

[Public Notice: 9836]

**30-Day Notice of Proposed Information Collection: Application to Determination Returning Resident Status**

**ACTION:** Notice of request for public comment.

**SUMMARY:** The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

**DATES:** The Department will accept comments from the public up to February 16, 2017.

**ADDRESSES:** Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email:* [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

**FOR FURTHER INFORMATION CONTACT:** Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Hector Perez-Casillas, who may be reached at [PRA\\_BurdenComments@state.gov](mailto:PRA_BurdenComments@state.gov).

**SUPPLEMENTARY INFORMATION:**

- *Title of Information Collection:* Application to Determine Returning Resident Status.
- *OMB Control Number:* 1405-0091.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Visa Office (CA/VO/L/R).

- *Form Number:* DS-0117.
- *Respondents:* Immigration Visa Petitioners.
- *Estimated Number of Respondents:* 4,400.
- *Estimated Number of Responses:* 4,400.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 2,200 hours.
- *Frequency:* Once.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

**Abstract of Proposed Collection**

Under INA Section 101(a)(27)(A) [8 U.S.C. 1101], Form DS-0117 is used by consular officers to determine the eligibility of an alien applicant for special immigrant status as a returning resident.

**Methodology**

The DS-0117 is available online. Applicants will fill out the application online, print the form, and submit the DS-0117 during their interview at a Consular Post.

**Edward Ramotowski,**

*Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.*

[FR Doc. 2017-00856 Filed 1-13-17; 8:45 am]

**BILLING CODE 4710-06-P**

**SURFACE TRANSPORTATION BOARD**

**Release of Waybill Data**

The Surface Transportation Board has received a request from University of California Davis (WB16-56-12/22/16) for permission to use certain unmasked

data from the Board's 1986-2015 Carload Waybill Samples. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

*Contact:* Alexander Dusenberry, (202) 245-0319.

**Brendetta S. Jones,**

*Clearance Clerk.*

[FR Doc. 2017-00814 Filed 1-13-17; 8:45 am]

**BILLING CODE 4915-01-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**Public Notice for Waiver of Aeronautical Land-Use Assurance**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of intent of waiver with respect to land; Chicago Midway International Airport, Chicago, Illinois.

**SUMMARY:** The FAA is considering a proposal to change 0.189 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at 5321 South Menard Avenue, Chicago, Illinois. The land is located off airport in a residential zoned area in Chicago, IL. This land is to be sold at Fair Market Value (FMV) to a locally-based business to be used as a parking lot. The land was purchased with federal funds under the Federal Aid to Airports Program (FAAP) and currently not used for aeronautical purposes. FAR Part 77, Right of Flight, and other compatible aeronautical land-uses would continue to be protected with deed restrictions required in the transfer of land ownership. The property is no longer needed for aeronautical use.

**DATES:** Comments must be received on or before February 16, 2017.

**ADDRESSES:** Documents are available for review by appointment at the FAA Chicago Airports District Office, Al Richardson, Program Manager, 2300 East Devon Avenue, Des Plaines, IL 60018, Telephone: (847) 294-7436/ [Al.Richardson@faa.gov](mailto:Al.Richardson@faa.gov); or at the Chicago Midway International Airport, Adam Rod, 10510 West Zemke Road, Chicago, IL 60666, 773-894-6907. Written comments on the Sponsor's

request must be delivered or mailed to: Al Richardson, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, IL 60018, Telephone Number: (847) 294-7436/FAX Number: (847) 294-7046.

**FOR FURTHER INFORMATION CONTACT:** Al Richardson, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, IL 60018. Telephone Number: (847) 294-7436/ *Al.Richardson@faa.gov*/FAX Number: (847) 294-7046.

**SUPPLEMENTARY INFORMATION:** In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The property was acquired by the City of Chicago Department of Aviation under the Federal Aid to Airports Program (FAAP) and currently not used for aeronautical purposes. This land is to be sold at Fair Market Value (FMV) to a locally-based business to be used as a parking lot. The land was purchased with federal funds under the Federal Aid to Airports Program (FAAP) and currently not used for aeronautical purposes. FAR Part 77, Right of Flight, and other aeronautical compatible land-uses will be protected by deed restrictions in the land transfer agreement.

The disposition of proceeds from the sale of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Chicago Midway International Airport, Chicago, Illinois from its obligations to be maintained for aeronautical purposes. Approval does not constitute a commitment by the FAA to financially assist in the change in use of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

*Property Description:* Lots 21 and 22 in block 20 in Crane Archer Avenue addition to Chicago, a subdivision of that part of the Southeast ¼ of Section 8, Township 38 North, Range 13, east of the Third Principal Meridian, lying North of Center Line of Archer Avenue, in Cook County, Illinois.

Issued in Chicago, IL, on January 3, 2017.  
**James G. Keefer,**  
*Manager, Chicago Airports District Office*  
*FAA, Great Lakes Region.*

[FR Doc. 2017-00753 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Supplemental Environmental Impact Statement: Hillsborough County, Florida

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of Intent to prepare a Supplemental Environmental Impact Statement/Section 4(f) Evaluation.

**SUMMARY:** The Federal Highway Administration (FHWA) in cooperation with the Florida Department of Transportation (FDOT) is issuing this notice to advise the public that a Supplemental Environmental Impact Statement/Section 4(f) Evaluation (SEIS/4f) will be prepared to evaluate new significant environmental impacts since the November 1996 approval of the Final Environmental Impact Statement/Section 4(f) Evaluation (FEIS) for the Tampa Interstate Study proposed highway project in Hillsborough County, Florida.

**FOR FURTHER INFORMATION CONTACT:** Cathy Kendall, Senior Environmental Protection Specialist, Federal Highway Administration, 3500 Financial Plaza, Suite 400, Tallahassee, Florida 32312, Telephone: (850) 553-2225, email: *Cathy.Kendall@dot.gov*. You may also contact Menna Yassin, Project Manager, Florida Department of Transportation District 7, 11201 North McKinley Drive, Tampa, Florida 33612, Telephone: 813-975-6433, email: *menna.yassin@dot.state.fl.us*.

**SUPPLEMENTARY PROJECT INFORMATION:** The FHWA, in cooperation with the Florida Department of Transportation will prepare an SEIS to examine the impacts and to modify the Long Term Preferred Alternative for the Tampa Interstate Study to improve portions of I-275 (SR 93), I-4 (SR 500) and SR 60 in Hillsborough County, Florida. The proposed modification includes changes to design elements and use of innovative financing sources, including collecting tolls.

A FEIS/Section 4(f) Evaluation (FEIS# FHWA-FL-EIS-95-03-F) was issued for the Project on November 22, 1996 with Records of Decision (ROD) dated January 31, 1997 and June 14, 1999. The FEIS and RODs are available on the

project Web site at:  
*www.TampaInterstateStudy.com*.

Since issuance of the RODs, the FDOT has taken several major steps to advance the Project toward construction: The documents have been reevaluated several times (in 2000, 2001, 2002, 2003, 2006, 2008, 2009, 2011, 2013 and 2015) which advanced various elements of the project, many of which have already been constructed: Including portions of Segment 1A, Segment 2A, Segment 3A, Segment 3B and Segment 3C. The FDOT now proposes to evaluate changes in environmental impacts, new information and circumstances relevant to the proposed project and changes to preliminary engineering identified since FEIS approval. An SEIS is being prepared because FHWA has determined that the changes result in significant impacts to the human and natural environment that were not evaluated in the FEIS. The SEIS is expected to examine:

- New impacts to the human, natural and physical environment.
- Adding overpasses at several locations along I-275 to improve local street access under I-275 to better connect the communities of Tampa Heights and VM Ybor.
- Tolling the Express Lanes of the Project's improvements along I-275 and I-4.
- Changes in express lane access to local streets in the Tampa downtown area, to the I-4/Selmon Expressway Connector, and various locations from the general use lanes on I-275 and I-4.

The proposed improvement would involve the reconstruction of I-275 from East of Howard Frankland Bridge to East of Himes Avenue, I-275 from East of Himes Avenue to East of Rome Avenue, and East of Rome Avenue to North of SR 574 (Dr Martin Luther King Jr Blvd.) and I-4 from I-275 to east of 50th Street. These improvements were identified as sections 1A, 2A, 2B, 3A and 3B in the originally approved FEIS. Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand.

Alternatives under consideration include: (1) Taking no further action; (2) the improvements shown in the Long Term Preferred Alternative (LTPA) in the approved FEIS, and (3) alteration of the LTPA to collect tolls for the express lanes, add more connectivity between the express lanes and the general use lanes, add express lane access to the local street network in downtown Tampa, and alter lane configuration slightly for improved future traffic operations.

Opportunities for input will be provided to appropriate federal, state,



and local agencies, and to private organizations and citizens who have expressed interest in this Project. Public meetings and a public hearing will be held to solicit public input. The SEIS will be made available for public and agency review and comment. Notices of availability for the SEIS will be provided through direct mail, the **Federal Register** and other media. Notification also will be sent to Federal, State, local agencies, persons, and organizations that submit comments or questions. Additional project information including schedules and locations for the public meetings/hearing will be announced in the local news media and on the Project Web site, [www.TampaInterstateStudy.com](http://www.TampaInterstateStudy.com).

To ensure that the full range of issues related to the proposed action is addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the SEIS should be directed to the FHWA at the address provided above. Questions concerning this Project and the SEIS may also be directed to Menna Yassin, Project Manager, Florida Department of Transportation, District 7, 11201 North McKinley Drive, Tampa, Florida 33612, telephone (813) 975-6433, email [menna.yassin@dot.state.fl.us](mailto:menna.yassin@dot.state.fl.us).

Pursuant to 23 U.S.C. 139, FHWA intends to combine the Final SEIS and Record of Decision if it is practicable, to the extent possible as allowed by this provision of law.

**Paperwork Reduction.** The Paperwork Reduction Act seeks, in part, to minimize the cost to the taxpayer of the creation, collection, maintenance, use, dissemination, and disposition of information. Consistent with this goal and with principles of economy and efficiency in government, FHWA tries to limit insofar as possible distribution of complete printed sets of NEPA documents. Accordingly, unless a specific request for a complete printed set of the NEPA document is received before the document is printed, FHWA and FDOT will distribute only electronic copies of the NEPA document. A complete printed set of the environmental document will be available for review at FDOT's offices; an electronic copy of the complete environmental document will be available on the Project Web site.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding inter-governmental consultation on

Federal programs and activities apply to this program.)

**Cathy Kendall,**

*Senior Environmental Specialist, FHWA, Tallahassee, Florida.*

[FR Doc. 2017-00810 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-22-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[Docket No. FTA-2015-0020]

#### Buy America Handbook—Conducting Pre-Award and Post-Delivery Audits for Rolling Stock Procurements

**AGENCY:** Federal Transit Administration, DOT.

**ACTION:** Notice of availability of Handbook.

**SUMMARY:** The Federal Transit Administration (FTA) has placed in the docket and on its Web site guidance, in the form of a Handbook, on complying with FTA's Buy America pre-award and post-delivery audit requirements for revenue service rolling stock procurements, from the solicitation phase through final acceptance of the rolling stock. The Handbook explains and illustrates how to calculate domestic content of rolling stock, and is intended for use by recipients of FTA funding, auditors, manufacturers, and suppliers (including subcontractors).

**DATES:** The Handbook becomes effective February 16, 2017.

**FOR FURTHER INFORMATION CONTACT:** For program questions, Patrick Centolanzi, FTA Office of Program Management, at (202) 366-0234 or [Patrick.Centolanzi@dot.gov](mailto:Patrick.Centolanzi@dot.gov). For legal questions, Cecelia Comito, FTA Office of Chief Counsel, at (202) 366-4011 or [Cecelia.Comito@dot.gov](mailto:Cecelia.Comito@dot.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Overview
- II. Comment Summary
  - A. General
  - B. Section 1—Introduction
  - C. Section 2—Pre-Award Audit
  - D. Section 3—Post-Delivery Audit
  - E. Section 4—Domestic Content Calculations
  - F. Section 5—Frequently Asked Questions
  - G. Appendices

##### I. Overview

FTA's objective in implementing 49 CFR part 661 (Buy America Requirements) and 49 CFR part 663 (Pre-Award and Post-Delivery Audits of Rolling Stock Purchases) is to support and promote the United States (U.S.)

manufacturing industry and U.S. jobs. As guidance on the pre-award and post-delivery audit requirements for rolling stock procurements, FTA published two separate Buy America handbooks in May 1995—*i.e.*, one for rail vehicle procurements and one for bus procurements.

Over the past several years, FTA has conducted Buy America Compliance Reviews, during which FTA observed and monitored the pre-award and post-delivery audit processes for fourteen capital grants. One primary finding was that FTA should provide more guidance and clarity on conducting pre-award and post-delivery Buy America audits as required in FTA's Buy America regulations (49 CFR parts 661 and 663).

As a result of that finding, FTA is issuing a new Buy America Handbook, entitled Conducting Pre-Award and Post-Delivery Audits for Rolling Stock Procurements (Handbook), which replaces the two Buy America handbooks on this subject from 1995. On June 16, 2015, FTA issued a notice of availability of the proposed handbook in the **Federal Register** (80 FR 34487) and requested public comment on the Handbook. The comment period closed on August 17, 2015. FTA received comments from 28 entities, including trade associations, State DOT's, metropolitan planning organizations, public transportation providers, manufacturers, and individuals. This notice addresses the comments received and explains the changes FTA made to the proposed handbook in response to the comments.

The updated Buy America Handbook explains to recipients how to verify and document compliance with FTA's Buy America pre-award and post-delivery audit requirements. In addition, the Handbook encourages recipients, manufacturers, and suppliers to adopt certain best practices to ensure compliance with the pre-award and post-delivery audit requirements. The Handbook applies only to rolling stock procurements that are subject to the pre-award and post-delivery audit requirements set forth in 49 CFR part 663.

This notice provides a summary of the comments received regarding the proposed Handbook and the changes made to the Handbook in response to those comments. The Handbook is not included in this notice; instead, the Handbook is available on FTA's Web site, at <https://www.transit.dot.gov/buyamerica>, and in the docket, at [www.regulations.gov](http://www.regulations.gov) (Docket No. FTA-2015-0020). Paper copies of the Handbook may be obtained by

contacting FTA's Administrative Services Help Desk, at (202) 366-4865.

### III. Comment Summary

#### A. General

Several commenters suggested changes for provisions in the Handbook that are identical to regulatory provisions in 49 CFR parts 661 and 663. FTA has not accepted any of these suggested changes as the rules can only be amended through the rulemaking process. However, where a careful read showed that the Handbook was not consistent with the regulations, we have made those changes to the Handbook to ensure the Handbook tracks the regulations. In addition, some commenters took the opportunity of a public comment process on the Handbook to make recommendations for amendments to FTA's Buy America regulation. FTA expects to update the Buy America regulation in the near future, and will consider comments received to the Handbook when developing the notice of proposed rulemaking.

A number of comments were outside the scope of the notice and thus are not addressed here. For example, a commenter recommended we include language in the Handbook from the DRIVE Act, which did not become law; however, we have updated the Handbook to reflect changes to 49 U.S.C. chapter 53, as amended by the Fixing America's Surface Transportation (FAST) Act, Public Law 114-94, Dec. 4, 2015. A number of commenters made editorial suggestions, which in many cases we accepted. Further, commenters asserted in a number of instances that the proposed Handbook went beyond the Buy America regulations. While we have not discussed each instance in this notice, we have thoroughly and carefully reviewed the Handbook to ensure it does not implicitly or explicitly require more than what is required by the regulations.

Throughout the document, FTA has made edits consistent with changes the FAST Act made to 49 U.S.C. 5323(j). For example, the Handbook no longer refers to "more than 60 percent of the cost" and instead refers to "more than the minimum percentage set forth in 49 U.S.C. 5323(j)(2)(C)(i)," or similar language, to reflect the phrasing in of higher minimum domestic content percentages for rolling stock between FY 2016 and FY 2020. As a second example, in section 1.2, Background, we added language from a new provision in 49 U.S.C. 5323(j)(5) that permits the cost of steel or iron that is produced in the United States and used in rolling stock

frames or car shells that are produced outside of the United States to be included in the calculation of the domestic content of the rolling stock when the average cost of a vehicle in the procurement exceeds \$300,000.

#### B. Section 1—Introduction

Section 1 of the proposed Handbook is an introductory chapter that provides a brief overview of the pre-award and post-delivery audit requirements set forth in 49 CFR parts 661 and 663, summarizes the contents of each subsequent section of the Handbook, and includes lists of relevant legal references, definitions, and acronyms.

Several commenters suggested that FTA clarify the Handbook applies only to new vehicles, and not to overhauls, rebuilds, or refurbished vehicles. We have clarified this in Subsection 1.1, Scope, and this notice therefore does not respond to comments inquiring as to how various provisions in the Handbook apply to overhauls, rebuilds, or refurbished vehicles, as those comments are outside the scope of the Handbook. We have also clarified that while Buy America requirements apply to support vehicles, the pre-award and post-delivery audit requirements apply only to vehicles used in revenue service.

Several commenters sought clarification on some of the defined terms used in the Handbook. Most of these comments related to terms that are defined in 49 CFR parts 661 and 663, and, as stated previously, FTA cannot make changes to those definitions outside of a rulemaking process. FTA has reviewed the definitions to ensure they are consistent with the regulations and made edits as appropriate. One commenter sought clarity on the use of the word "independent" in the definition of the term auditor; we have amended the definition to be consistent with the use of the term in the text of the Handbook, and the definition now states the auditor must be independent from the manufacturer and the manufacturer's agents.

#### C. Section 2—Pre-Award Audit

Section 2 describes the pre-award audit requirements set forth in 49 CFR 663.21-27 and explains that the recipient must ensure the pre-award audit is complete before the recipient enters into a formal contract for the purchase of rolling stock. Pursuant to 49 CFR 663.23, the pre-award audit must include: A Pre-Award Buy America Certification, a Pre-Award Purchaser's Requirements Certification, and, where appropriate, a Pre-Award Certification of Compliance with or Inapplicability of

Federal Motor Vehicle Safety Standards (FMVSS).

Two commenters sought clarity on how to determine whether an auditor is "qualified." FTA has not attempted to define who is a "qualified" auditor in the Handbook, and instead relies on its recipients to make that determination. One commenter asked what "independent from the procurement process" means; specifically, whether an entity that develops and writes the specifications for a procurement would be barred from conducting Buy America audits. The original intent was that the auditor be independent from the manufacturer; we have amended the text of the Handbook by removing the requirement that an auditor be independent from the procurement process.

Several commenters had questions related to Buy America waivers. Two commenters asked what timeframe should be allowed to request, and be granted, a Buy America waiver. Some commenters wanted to know how far in advance a Buy America waiver should be requested before the contract is awarded. FTA cannot provide a definitive timeline for processing waiver requests, and recommends recipients make those requests as soon as they can. One commenter stated the Handbook was not clear as to whether waivers applied to components or to the whole vehicle. Another commenter questioned the assertion in the Handbook that a price differential waiver may be granted if including the domestic material would increase the cost of the overall project by more than 25 percent, stating the regulation provides the waiver may be granted if the price of a single component is increased by 25 percent. The discussion of Buy America waivers in section 2.2.1 of the Handbook has been revised to clarify the applicability of the three statutory waivers in 49 U.S.C. 5323(j)(2) to rolling stock procurements. By statute, the procurement of rolling stock is subject to a waiver from the requirement that manufactured goods must contain 100 percent domestic content. Section 5323(j)(2)(C) allows FTA to waive Buy America requirements for rolling stock procurements by permitting domestic content less than 100 percent. The Buy America statute also includes three additional waivers: Public interest waivers; non-availability waivers; and price differential waivers. The procedures for applying for each statutory waiver are set forth in 49 CFR 661.7. Only waivers based on public interest or non-availability may be granted for a component or subcomponent in the case of the

procurement of rolling stock. 49 CFR 661.7(f).

Public interest and non-availability waivers under 49 CFR 661.7(f) may be granted for components and subcomponents of rolling stock, and if a waiver is granted, the component or subcomponent will be considered to be of domestic origin for purposes of calculating the domestic content of the vehicle. Generally, recipients, not the manufacturer, must apply for the Buy America waiver. However, a potential bidder, offeror or supplier may seek a public interest or non-availability waiver for a component or subcomponent.

Several commenters expressed concern about the level of documentation that recipients should review and maintain. The language in the Handbook in section 2.2.1. and 2.2.2, listing the documents the recipient must review and maintain for the procurement, closely tracks the regulation at 49 CFR part 663, in particular §§ 663.23, 633.25, and Appendix D to 49 CFR 661.11. Further, an auditor must review the manufacturer's documentation that provides support for the stated costs of the components, subcomponents, and final assembly. This is part of the auditing process—verifying that the represented costs are accurate. If the manufacturer declines to provide supporting documentation for component and subcomponent costs, the Buy America domestic content cannot be verified, and the auditor will need to include this information in the pre-award audit report. The auditor needs to review enough supporting documentation to be satisfied that the vehicles will be compliant with Buy America requirements. FTA has amended the Handbook text in subsection 2.2.2. to provide guidance on maintaining confidentiality of manufacturer's proprietary information.

Commenters had similar questions about auditors reviewing documentation related to final assembly. Notably, the list of items to review is a suggested list (“ . . . the auditor may perform due diligence through a variety of methods, including . . .”). One commenter suggested that including proposed final assembly costs in the Pre-Award Buy America Compliance Certification is not required by the regulation. Section 663.25 of title 49, CFR, specifically requires the recipient or its auditor to review “a description of the activities that will take place at the final assembly point and the cost of final assembly.” For pre-award, FTA acknowledges these will be estimated costs, and the

Handbook uses the words “proposed” and “estimated.”

Some manufacturers also had concerns about how they could confirm their suppliers' compliance with Buy America, stating they rely on their supplier's certification of compliance, particularly given the large number of suppliers, components and subcomponents. Some objected to the recommended best practices identified in subsection 2.2.3.4. for confirming compliance. To the extent the manufacturer is asserting that components and subcomponents should be calculated as part of the domestic content of a vehicle, the manufacturer needs to be confident that its suppliers have provided compliant parts. The manufacturer will need to determine whether to take additional steps to confirm compliance with Buy America. FTA has provided some recommendations in the Handbook; this is neither an exhaustive list nor a list of required activities. One commenter suggested that FTA should require manufacturers to obtain executed certifications of compliance from their suppliers, as opposed to FTA simply recommending that manufacturers obtain such certifications. FTA has not made this a requirement in the past and it is not a requirement in the regulations, so we have maintained the provision in the Handbook as a recommendation.

One commenter objected to language in subsection 2.3.2.2. that suggests recipients should verify a manufacturer's financial viability as part of the review to certify compliance with the pre-award requirements. The commenter asserted this statement does not belong in the Buy America Handbook. Under 49 CFR 663.27, Pre-award purchaser's requirements certification, the recipient must keep on file a certification that the proposed manufacturer is a “responsible manufacturer with the capability to produce a vehicle that meets the recipient's specification set forth in the recipient's solicitation.” Financial viability is an important characteristic of a “responsible manufacturer,” and FTA has retained the language.

#### *D. Section 3—Post-Delivery Audit*

Section 3 describes the post-delivery audit requirements set forth in 49 CFR 663.31–39. It explains that the recipient must ensure the post-delivery audit is complete after the rolling stock is delivered to the recipient but before title to the rolling stock is transferred to the recipient, or before the rolling stock is put into revenue service, whichever comes first. Pursuant to 49 CFR 663.33,

the post-delivery audit must include: A Post-Delivery Buy America Certification, a Post-Delivery Purchaser's Requirements Certification (based upon a review of the Resident Inspector's Report pursuant to 49 CFR 663.37), and a Post-Delivery Certification of FMVSS Compliance or Inapplicability, where appropriate. This section explains the requisite processes and documentation requirements for each of the post-delivery audit certifications listed above.

This section also describes best practices to aid recipients, manufacturers, and suppliers in achieving compliance with the post-delivery audit requirements, including guidance on how to prepare the requisite Resident Inspector's Report and supporting documentation, in accordance with 49 CFR 663.37, and procedures for effectively verifying compliance with the domestic content and U.S. final assembly requirements.

Several commenters noted inconsistencies in how the proposed Handbook described the post-delivery period. We have amended the Handbook to track the language used in the regulation. In response to comments, we have clarified that Post-Delivery Domestic Content Monitoring (also described as “intermediate audits”) is a recommended best practice that would occur after the vehicle manufacturer delivers the first vehicle to the recipient and until the vehicle manufacturer transfers title to the last vehicle to the recipient or the recipient puts the last vehicle into revenue service, whichever is first. Specifically, FTA added subsection 3.1.3.4 to the Handbook to address the concerns regarding post-delivery monitoring raised by the commenters.

Several commenters expressed concern regarding the possibility of having to produce proprietary information to show Buy America compliance. FTA has amended the Handbook to address these concerns, in sections 2 and 3 and an added “FAQ” in section 5. If a manufacturer is concerned about releasing proprietary information, the manufacturer and recipient may agree that the recipient will contract with an external consultant to conduct the manufacturer's Buy America certification review. Alternatively, the recipient may be able to keep its Buy America audit function independent by using a “firewall” and assuring the manufacturer that those employees of the recipient performing the Buy America audit are prohibited from disclosing any of the manufacturer's proprietary data. Further, the review of

documents may occur at the manufacturer's place of business. There is no requirement that the recipient or its auditors obtain copies of the documents; they need simply to review them. Whether conducted by a contractor or the recipient's employees, the manufacturer may require the reviewer to sign a non-disclosure agreement prior to reviewing the documents.

We also have amended the Handbook to track the regulation with regard to the information the recipient must keep on file. The recipient is not required to maintain a list of components and subcomponents and their costs for a procured vehicle—the recipient is required to review that information (as provided by the manufacturer), or have an independent auditor review that information, and certify that it is satisfied that the rolling stock meets the Buy America requirements.

One commenter asked if a Post-Delivery Audit is required if FTA granted a waiver from the Buy America requirements. There may be situations in which a full or partial audit would still be required, and FTA will address post-delivery audit requirements in the letter granting any waiver from Buy America requirements. In the event FTA issues a general waiver for a certain class of vehicles, if the **Federal Register** notice describing the waiver does not discuss pre-award or post-delivery audit requirements, recipients are encouraged to contact their FTA regional office for assistance. The same commenter asked for what purpose is the cost of final assembly used. Reviewing the cost of final assembly helps to verify the manufacturer is completing the activities that are required in final assembly, and the regulation at 49 CFR 663.25(b) requires recipients or their auditors to verify these costs.

As with other sections of the Handbook, FTA has made edits to clarify intent, to ensure consistency with the regulations, and to improve readability.

#### *E. Section 4—Domestic Content Calculations*

This section provides guidance on how to calculate domestic content correctly for rolling stock procurements in accordance with 49 CFR 661.11, providing guidance relevant to both the pre-award audit and the post-delivery audit.

The introductory portion of this section has been amended to better explain how to conduct a proper Domestic Content Calculation consistent with 49 CFR 661.11. FTA has observed that some recipients and vendors, or

their agents or auditors, are calculating the domestic content amount by dividing the total costs of the domestic components by the estimated value of the vehicle, found by subtracting certain costs from the Contract Total Price of the vehicles. This calculation is not consistent with 49 CFR 661.11 and fails to demonstrate compliance. Additional information is included to add instruction for doing a proper Domestic Content Calculation consistent with 49 CFR 661.11.

Commenters generally objected to the inclusion of the total contract price or total vehicle cost in the analysis, as those values are not relevant to the Buy America domestic content calculations, which are based on vehicle material costs. FTA agrees with commenters and we have removed the subsections addressing these values, and have also removed references to the total contract price and total vehicle cost from the rest of the Handbook.

In response to comments, we have made edits to subsection 4.3, which provides a sample Domestic Content Worksheet with detailed step-by-step instructions for how to fill out the worksheet and calculate domestic content. Commenters generally sought clarification on the required domestic content and how that calculation affects the step by step analysis in the worksheet. Similarly, the commenters raised questions about how the cost of the components (foreign and domestic) and subcomponents affect the calculations. We have included references to the regulations as well as additional text to add clarity to the spreadsheets.

A number of commenters objected to the list of "Non-Recurring Expenses" or NREs, described in subsection 4.4. As with the total contract price and total vehicle price, FTA agrees with commenters that these values are not necessary for the calculation of domestic content for Buy America purposes. Given the regulation describes the cost of a component or subcomponent as the price a bidder or offeror pays, the NREs are already captured in the retail price of the component or subcomponent.

As with other sections of the Handbook, FTA has made edits in section 4 for clarity and consistency with the regulations.

#### *F. Section 5—Frequently Asked Questions*

Section 5 addresses some of the most frequently asked questions (FAQs) about pre-award and post-delivery audits. Among numerous other topics, the FAQs concern what types of rolling

stock are not subject to the pre-award and post-delivery audit requirements; how to calculate domestic content; and the responsibilities of the resident inspector. The majority of comments to this section addressed inconsistencies or perceived inconsistencies between the FAQs and the rest of the Handbook, the regulations, or the statute. FTA has carefully reviewed section 5 and made edits as appropriate. In addition, for clarity, we have added the regulatory citations to the FAQs where appropriate, and, at the suggestion of commenters, added an FAQ related to confidentiality of manufacturer's proprietary information.

#### *G. Appendices*

The proposed Handbook contained four appendices. The appendices provide sample forms, spreadsheets and format for a resident inspector's report. These are samples only and, with the exception of the two Buy America certification forms (B.1 and B.2) in Appendix B, which are required by the regulations, recipients may choose to use their own forms, spreadsheets, and format for the resident inspector's report, provided the recipient's forms, etc., contain the information required by the regulations.

In the proposed Handbook, FTA included Appendix A, which contained domestic content calculation worksheets, including one worksheet for rail vehicles and one worksheet for buses. Commenters noted that some of the identified "components" in Appendix A are not included in Appendices B and C to 49 CFR 661.11. Commenters asserted that, absent a rulemaking, the components included in Appendix A of the Handbook should track the appendices to section 661.11. While Appendices B and C to section 661.11 note that the list of components is not exhaustive, FTA agrees that the Handbook is not the appropriate vehicle to "officially" expand on that list. Given that Appendix A contained information not consistent with the regulations, and that Section 4 contains step-by-step instructions for calculating domestic content, we have removed Appendix A in its entirety and re-numbered the other three appendices accordingly.

Appendix A in the final Handbook, as so re-numbered, contains sample compliance checklists for recipients, manufacturers, and suppliers to use in order to ensure that the Pre-Award and Post-Delivery Buy America Certifications and Purchaser's Requirements Certifications are properly completed. This appendix also contains a sample Resident Inspector's Report, which the recipient must review before

completing its Post-Delivery Purchaser's Requirements Certification. In response to comments, FTA made edits for clarity and for consistency with the regulations.

Appendix B contains sample pre-award and post-delivery certificates and forms. These samples are intended to aid recipients, manufacturers, and suppliers in complying with the 49 CFR parts 661 and 663 requirements, and these samples may be utilized and filled out by these parties, where appropriate. In response to comments, FTA made edits for clarity and for consistency with the regulations.

Appendix C contains a sample pre-award audit report and a sample post-delivery audit report, including necessary certifications and recommended supporting documentation. In response to comments, FTA made edits for clarity and for consistency with the regulations. FTA also made edits to simplify the sample reports.

Ellen Partridge,  
Chief Counsel.

[FR Doc. 2017-00873 Filed 1-13-17; 8:45 am]

BILLING CODE P

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[FTA Docket No.]

#### Notice of Request for Revision of a Currently Approved Information Collection

**AGENCY:** Federal Transit Administration, DOT.

**ACTION:** Notice of request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the revision of the following information collection: Metropolitan and Statewide and Nonmetropolitan Transportation Planning.

**DATES:** Comments must be submitted before March 20, 2017.

**ADDRESSES:** To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's)

electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at [www.regulations.gov](http://www.regulations.gov). Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202-493-2251.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

**Instructions:** You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to [www.regulations.gov](http://www.regulations.gov). You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit

[www.regulations.gov](http://www.regulations.gov). Docket: For access to the docket to read background documents and comments received, go to [www.regulations.gov](http://www.regulations.gov) at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Metropolitan and Statewide and Nonmetropolitan Transportation Planning—Mr. Dwayne Weeks, Office of Planning and Environment, (202) 493-0316, or email: [dwayne.weeks@dot.gov](mailto:dwayne.weeks@dot.gov).

**SUPPLEMENTARY INFORMATION:** Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the

collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

**Title:** Metropolitan and Statewide and Nonmetropolitan Transportation Planning (OMB Number: 2132-0529).

**Background:** The FTA and Federal Highway Administration (FHWA) jointly carry out the federal mandate to improve urban and rural transportation. 49 U.S.C. 5303 and 5304 and 23 U.S.C. 134 and 135 authorize the use of federal funds to assist Metropolitan Planning Organizations (MPOs), States, and local public bodies in developing transportation plans and programs to serve the transportation needs of urbanized areas over 50,000 in population and other areas of States outside of urbanized areas. The information collection activities involved in developing the Unified Planning Work Program (UPWP), the Metropolitan Transportation Plan, the Long-Range Statewide Transportation Plan, the Transportation Improvement Program (TIP), and the Statewide Transportation Improvement Program (STIP) are necessary to identify and evaluate the transportation issues and needs in each urbanized area and throughout every State. These products of the transportation planning process are essential elements in the reasonable planning and programming of federally funded transportation investments.

In addition to serving as a management tool for MPOs, the UPWP is used by both FTA and FHWA to monitor the transportation planning activities of MPOs. It also is needed to establish national out year budgets and regional program plans, develop policy on using funds, monitor State and local compliance with technical emphasis areas, respond to Congressional inquiries, prepare Congressional testimony, and ensure efficiency in the use and expenditure of Federal funds by determining that planning proposals are both reasonable and cost-effective. 49 U.S.C. 5303 and 23 U.S.C.134(j) require the development of TIPs for urbanized areas; STIPs are mandated by 49 U.S.C. 5304 and 23 U.S.C. 135(g) for an entire State. After approval by the Governor and MPO, metropolitan TIPs in attainment areas are to be incorporated directly into the STIP. For nonattainment areas, FTA/FHWA must make a conformity finding on the TIPs before including them in the STIP. The complete STIP is then jointly reviewed and approved or disapproved by FTA and FHWA. These conformity findings and approval actions constitute the determination that States are complying

with the requirements of 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304 as a condition of eligibility for federal-aid funding. Without these documents, approvals and findings, FTA and FHWA cannot provide capital and/or operating assistance.

The FTA and FHWA updated their method for estimating the annual burden hours of the transportation planning programs on respondents to reflect the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning. On July 6, 2012, the President signed into law Public Law 112-141, the Moving Ahead for Progress in the 21st Century Act (MAP-21) and on December 4, 2015, signed into law Public Law 114-94, the Fixing America's Surface Transportation Act (FAST). The MAP-21 makes significant changes to the statewide and nonmetropolitan planning process and the metropolitan transportation planning process, and the FAST makes minor changes to existing provisions. As a result, FHWA and FTA have issued a final rule that makes the regulations consistent with current statutory requirements. The rule is central to the implementation of the overall performance management framework created by MAP-21.

The changes to the FHWA/FTA statewide and nonmetropolitan and metropolitan transportation planning regulations (23 CFR part 450 and 49 CFR part 613) make the regulations consistent with current statutory requirements. Major regulatory revisions include a new mandate for States and MPOs to take a performance-based approach to planning and programming; a new emphasis on the nonmetropolitan transportation planning process, by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing a process for the creation of regional transportation planning organizations (RTPOs); a structural change to the membership of the larger MPOs; a new framework for voluntary scenario planning; and a process for programmatic mitigation plans. The revised burden hour estimates reflect the annual compliance burden of the requirements in the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning published on May 27, 2016.

*Respondents:* State Departments of Transportation and MPOs.

*Estimated Annual Burden on*

*Respondents:* 9,109 hours for each of the 461 respondents.

*Estimated Total Annual Burden:*

4,199,279 hours.

*Frequency:* Annual.

**William Hyre,**

*Deputy Associate Administrator for Administration.*

[FR Doc. 2017-00874 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-57-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[Docket No. FTA-2016-0041]

#### Proposed General Directive 17-1; Stop Signal Overruns on Rail Fixed Guideway Public Transportation Systems

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notice of proposed general directive; request for comments.

**SUMMARY:** FTA has placed in the docket and on its Web site a proposed General Directive to address safety risks associated with stop signal overruns. The proposed directive follows FTA's review and analysis of data and information submitted in response to the agency's *Safety Advisory 16-1: Stop Signal Overruns*, for Rail Fixed Guideway Public Transportation System operations during calendar year 2015.

**DATES:** Comments must be received by March 20, 2017. Any comments filed after this deadline will be considered to the extent practicable.

**ADDRESSES:** Please identify your submission by Docket Number [FTA-2016-0041] through one of the following methods:

- *Federal eRulemaking Portal:* Submit electronic comments and other data to <http://www.regulations.gov>.
- *U.S. Mail:* Send comments to Docket Operations; U.S. Department of Transportation; 1200 New Jersey Avenue SE., Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building, Ground Floor, at 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations, U.S. Department of Transportation, at (202) 493-2251.

*Instructions:* You must include the agency name (Federal Transit Administration) and Docket Number (FTA-2016-0041) for this notice at the beginning of your comments. Due to security procedures in effect since October 2001, mail received through the U.S. Postal Service may be subject to

delays. Parties submitting comments should consider using an express mail firm to ensure their prompt filing of any submissions not filed electronically or by hand. If you wish to receive confirmation that FTA received your comments, you must include a self-addressed stamped postcard. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. You may review U.S. DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000, at 65 FR 19477 or <http://DocketsInfo.dot.gov>.

*Electronic Access and Filing:* This document and all comments received may be viewed online through the Federal eRulemaking portal at <http://www.regulations.gov>. Assistance and guidelines for electronic submission and retrieval are available on the Web site 24 hours each day, 365 days a year. Please follow the instructions. An electronic copy of this document may be downloaded from the Office of Federal Register's home page at <https://www.federalregister.gov>.

**FOR FURTHER INFORMATION CONTACT:** For program matters, Candace Key, Acting Director, Office of System Safety, (202) 366-9178 or [Candace.Key@dot.gov](mailto:Candace.Key@dot.gov) or Aloha Ley, Chief, Safety Assurance and Risk Management Division, (202) 366-4979 or [Aloha.Ley2@dot.gov](mailto:Aloha.Ley2@dot.gov). For legal matters, Scott Biehl, Senior Counsel, (202) 366-0826 or [Scott.Biehl@dot.gov](mailto:Scott.Biehl@dot.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with 49 CFR 670.25, the Federal Transit Administration (FTA) is proposing a General Directive to address the combination of unsafe conditions and practices that lead to stop signal overruns and the risks of death or personal injury or damage to property or equipment. The proposed directive follows FTA's review and analysis of data and information submitted in response to the agency's *Safety Advisory 16-1: Stop Signal Overruns*, for rail transit operations during calendar year 2015. FTA's review of the data and information gathered in response to *Safety Advisory 16-1: Stop Signal Overruns*, for rail transit operations during calendar year 2015 indicates that RFGPTSs experience stop signal overruns with varying frequencies, and that most SSOAs do not actively investigate these events. Further, the responses to *Safety Advisory 16-1* indicate a lack of standard practice, definitions and requirements in the rail transit industry to protect against unauthorized passing of stop signals.

FTA requests public comment on this proposed General Directive, which is available in its entirety on the FTA public Web site at <http://www.transit.dot.gov/tso.html> and in Docket No. FTA-2016-0041 at [www.regulations.gov](http://www.regulations.gov). Following a summary and analysis of the public comment, FTA will issue a final General Directive, and a notice of the availability of that final General Directive in the **Federal Register**, with a Web link to the agency's responses to the public comment.

**Carolyn Flowers,**

*Acting Administrator.*

[FR Doc. 2017-00793 Filed 1-13-17; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2016-0154; Notice No. 2016-23]

#### Hazardous Materials: Information Collection Activities

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

**ACTION:** Notice and request for comments on Information Collection Approvals.

**SUMMARY:** This notice announces Office of Management and Budget (OMB) approval and extension for four Information Collection Requests (ICRs). Specifically, this notice announces the following: OMB approval and extension until February 28, 2018 for OMB Control No. 2137-0586, "Hazardous Materials Public Sector Training & Planning Grants"; OMB approval and extension until March 31, 2019 for OMB Control No. 2137-0628, "Flammable Hazardous Materials by Rail Transportation"; and OMB approval and extension until June 30, 2019 for both OMB Control No. 2137-0613, "Subsidiary Hazard Class and Number/Type of Packagings," and OMB Control No. 2137-0510, "Radioactive (RAM) Transportation Requirements."

**DATES:** The expiration dates for the ICRs approved by OMB are February 28, 2018; March 31, 2019; or June 30, 2019, as indicated under the **SUPPLEMENTARY INFORMATION** section of this notice.

**ADDRESSES:** Requests for a copy of an information collection should be directed to Steven Andrews or T. Glenn Foster, Office of Hazardous Materials Standards (PHH-12), Pipeline and

Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

**FOR FURTHER INFORMATION CONTACT:** Steven Andrews or T. Glenn Foster, Office of Hazardous Materials Standards (PHH-12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590-0001, Telephone (202) 366-8553.

**SUPPLEMENTARY INFORMATION:** OMB regulations (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* 5 CFR 1320.8(s)) and specify that no person is required to respond to an information collection unless it displays a valid OMB control number. In accordance with the Paperwork Reduction Act of 1995, PHMSA has received OMB approval for renewal of the following ICRs:

*OMB Control Number:* 2137-0586.  
*Title:* "Hazardous Materials Public Sector Training & Planning Grants."  
*Expiration Date:* February 28, 2018.  
*OMB Control Number:* 2137-0628.  
*Title:* "Flammable Hazardous Materials by Rail Transportation."  
*Expiration Date:* March 31, 2019.  
*OMB Control Number:* 2137-0613.  
*Title:* "Subsidiary Hazard Class and Number/Type of Packagings."  
*Expiration Date:* June 30, 2019.  
*OMB Control Number:* 2137-0510.  
*Title:* "Radioactive (RAM) Transportation Requirements."  
*Expiration Date:* June 30, 2019.

Issued in Washington, DC, on January 11, 2017.

**William S. Schoonover,**

*Associate Administrator, Pipeline and Hazardous Materials Safety Administration.*

[FR Doc. 2017-00828 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-60-P**

## DEPARTMENT OF TRANSPORTATION

### Solicitation of Proposals for Designation of Beyond Traffic Innovation Centers

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Notice of intent to designate Beyond Traffic Innovation Centers.

**SUMMARY:** *Beyond Traffic* is the Department of Transportation's ("DOT" or the "Department") draft 30-year framework for the future (the full report

can be found here: <https://www.transportation.gov/BeyondTraffic>). It lays out key trends that will affect the future of our transportation system. To further this understanding, the DOT is requesting proposals from applicants to form an initial network of multiple centers, focused—through academic activities and programs—on delivering solutions to the challenges outlined in *Beyond Traffic*. These entities will be designated as "USDOT Beyond Traffic Innovation Centers" and will serve as thought leaders responsible for continuing the conversation surrounding the future of transportation. USDOT Beyond Traffic Innovation Center activities could include identifying possible solutions in their megaregion (*Beyond Traffic*, p. 25), including but not limited to: Evaluating and researching new technologies relevant to tackling transportation challenges with the megaregion, identification and development of training approaches for the megaregion's future transportation workforce, and convening practitioners, public and private leaders within the megaregion to help identify specific actions that can be taken in the megaregion to address its challenges over the 30 years.

**DATES:** Proposals must be submitted by 11:59 p.m. EST on December 21, 2016.

**ADDRESSES:** Final proposals must not exceed 4 pages in length, and must be submitted electronically to: [BeyondTraffic@dot.gov](mailto:BeyondTraffic@dot.gov).

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this notice, please contact [BeyondTraffic@dot.gov](mailto:BeyondTraffic@dot.gov).

**SUPPLEMENTARY INFORMATION:** The Department is requesting applications to be designated as a USDOT Beyond Traffic Innovation Center. Read this notice in its entirety so that you have all the information you need to determine whether you would like to submit a proposal.

*Description:* In the enabling legislation that established the DOT, the Secretary of Transportation is vested with the responsibility to report on current and future conditions of our transportation system. With the Nation's transportation system experiencing repeated impacts due to population growth, changes in climate, a stressed freight network, and inaction to address these impacts, such a discourse could not come at a more crucial time. *Beyond Traffic 2045: Trends and Choices* has been developed by a team of Departmental experts, with input from the public, to conduct a comprehensive examination of our Nation's transportation system. In the fall of



2015, Secretary Foxx and his team travelled to eleven emerging megaregions to solicit feedback on the draft report. Specifically, communities provided feedback on the gaps in opportunity exacerbated by disparities in transportation access and past infrastructure decisions. The designated USDOT Beyond Traffic Innovation Centers will help to continue this conversation in their respective megaregions, including, but not limited to: Evaluating and researching new technologies relevant to tackling transportation challenges with the megaregion, identification and development of training approaches for the megaregion's future transportation workforce, and convening practitioners, public and private leaders with the megaregion to help identify specific actions that can be taken in the megaregion to address its challenges over the 30 years. For this purpose, the DOT is seeking applications from eligible entities that would like to be designated as a USDOT Beyond Traffic Innovation Center. The Centers will form a community of forward-thinking researchers, students, and thought leaders who can help drive our Nation's transportation systems forward by addressing the following questions:

- How will we move? How will we build a transportation system to accommodate a growing population and changing travel patterns?
- How will we move things? How will we reduce freight chokepoints that drive up the cost of owning a business?
- How will we move better? How will we knock down barriers to new technologies that promise to make travel safer and more convenient?
- How will we adapt? How will we make our infrastructure resilient to more frequent catastrophic weather events?
- How will we grow opportunity for all Americans?
- How will we align decisions and dollars, and invest the trillions of dollars our transportation system needs in the smartest way possible?

USDOT Beyond Traffic Innovation Centers will be recognized by the Department of Transportation as forward-thinking and influential institutions that are capable of driving solutions to the challenges identified in *Beyond Traffic*, through research, curriculum, outreach, and other activities.

**Designation Decisions:** The Secretary of Transportation will make all designations under this notice. A designation as a USDOT Beyond Traffic Innovation Center is not an award of Federal financial assistance.

**Eligibility Information:** The following entities are eligible for designation as a USDOT Beyond Traffic Innovation Center. Individuals are not eligible for designation under this notice. The Department actively encourages the inclusion of minority-serving institutions. Eligible entities include:

- U.S. non-profit institutions of higher education as defined under 20 U.S.C. 1001(a). Non-profit institutions of higher education may include qualifying two-year institutions that meet the requirements of 20 U.S.C. 1001(a). This includes existing and future University Transportation Centers and applicants.
- Non-profit organizations described under section 501(c)(3) of the Internal Revenue Code of 1986 (IRC) and exempt from tax under section 501(a) of such code.

**Selection Criteria:** The Secretary of Transportation will make all designations. Selections will be based on the applicant's submittal in response to the information required immediately below:

Applications must include the following:

- Commitment to continuing the conversation launched by *Beyond Traffic*, as demonstrated through a clear action plan for furthering these ideas, such as transportation solutions for their megaregion, including, but not limited to: Evaluating and researching new technologies relevant to tackling transportation challenges with the megaregion, identification and development of training approaches for the megaregion's future transportation workforce, and convening practitioners, public and private leaders with the megaregion to help identify specific actions that can be taken in the megaregion to address its challenges over the 30 years. A designated *Beyond Traffic* Coordinator who will commit to participating in future events related to megaregion development with USDOT must be named as part of the application.

DOT will also consider the following:

- The extent to which the applicant demonstrates the commitment outlined above and administers an established academic or outreach program.
- The capability of the applicant to provide leadership in making national and regional contributions to the conversation around the future of our transportation system.
- The applicant's ability and willingness to maintain a working relationship with the Department's relevant research program offices. The application should describe this proposed relationship, including

aspects such as potential participation in conferences, meetings, joint research efforts, and submission of activity reports to the DOT on a routine basis.

- The extent to which the State or locality in which the applicant is located can provide applicable solutions for the broader region and surrounding corridor for improved mobility through the advancement of emerging technologies.

- The demonstrated research and extension resources available to the applicant for carrying out activities and programs as they relate to *Beyond Traffic*.

**Review And Selection Process:** DOT will review all applications received by the deadline. The designation review and selection process consists of two phases: Eligibility & Technical Review and Senior Review. In the Eligibility & Technical Review phase, DOT staff will (1) ensure that the applicant is eligible (see Eligibility Information section) and (2) assess the applicant's ability to meet the mandatory criteria and one or more of the other Selection Criteria enumerated above. In the Senior Review phase, which includes senior leadership from DOT, specific applications may be advanced to the Secretary for selection. In making recommendations, the Senior Review team may seek to ensure the inclusion of minority-serving institutions. The Secretary may select from applications advanced by the Senior Review team for designations.

**Designation Notice:** The Secretary will announce designations by posting a list of USDOT Beyond Traffic Innovation Centers at [www.transportation.gov/BeyondTraffic](http://www.transportation.gov/BeyondTraffic). The Department anticipates that the selection of the initial USDOT Beyond Traffic Innovation Centers will be completed during the first quarter of calendar year 2017. The Department may make additional designations on an annual basis or as deemed appropriate.

**Designation Agency Contacts:** For further information concerning this notice, please contact the Department via email at [BeyondTraffic@dot.gov](mailto:BeyondTraffic@dot.gov).

**Other Information:** All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information you consider to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission "Contains Confidential Business Information (CBI)"; (2) mark each affected page "CBI"; and (3)

highlight or otherwise denote the CBI portions. DOT protects such information from disclosure to the extent allowed under applicable law. In the event DOT receives a Freedom of Information Act (FOIA) request for the information, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.17. Only information that is ultimately determined to be confidential under that procedure will be exempt from disclosure under FOIA.

Dated: December 6, 2016.

**Anthony R. Foxx,**

*Secretary.*

[FR Doc. 2017-00824 Filed 1-13-17; 8:45 am]

**BILLING CODE 4910-9X-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### Sanctions Actions Pursuant to Executive Order 13224

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of 4 individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism."

**DATES:** OFAC's actions described in this notice were effective on January 10, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Associate Director for Global Targeting, tel.: 202/622-2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622-2490, Assistant Director for Licensing, tel.: 202/622-2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622-2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site ([www.treas.gov/ofac](http://www.treas.gov/ofac)).

##### Notice of OFAC Actions

On January 10, 2017, OFAC blocked the property and interests in property of the following 4 individuals pursuant to E.O. 13224, "Blocking Property and Prohibiting Transactions With Persons

Who Commit, Threaten To Commit, or Support Terrorism":

#### Individuals

1. SHARROUF, Khaled (a.k.a. ZARQAWI AL AUSTR, Abu; a.k.a. ZARQAWI AUSTRALI, Abu; a.k.a. ZARQAWI, Abu), Syria; Iraq; DOB 23 Feb 1981; POB Auburn, New South Wales, Australia; nationality Australia; Gender Male; Passport L3135591 (Australia); alt. Passport L5210356 (Australia); alt. Passport N723649 (Australia); Driver's License No. 12789234 (Australia) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

2. PRAKASH, Neil Christopher (a.k.a. KHALED AL-CAMBODI, Abu), Syria; Iraq; DOB 07 May 1991; POB Melbourne, Australia; nationality Australia; Gender Male; Passport N4325853 (Australia) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

3. ROCHMAN, Oman (a.k.a. ABDULROHMAN, Oman; a.k.a. ABDURAHMAN, Aman; a.k.a. ABDURRACHMAN, Aman; a.k.a. ABDURRAHMAN AL-ARKHABILIY, Abu Sulaiman Aman; a.k.a. ABDURRAHMAN, Aman; a.k.a. ABDURRAHMAN, Oman; a.k.a. RAHMAN, Aman Abdul; a.k.a. RAHMAN, Oman), Pasir Putih Prison, Nusa Kambangan Island, Indonesia; DOB 05 Jan 1972; POB Sumedang, Indonesia; nationality Indonesia; Gender Male; Ustadz (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

4. USMAN, Bachrumsyah Mennor (a.k.a. SYAH, Bahrum; a.k.a. "BACHRUMSHAH"; a.k.a. "BACHRUMSYAH"; a.k.a. "BAHRUMSYAH"; a.k.a. "IBRAHIM, Abu"; a.k.a. "MUHAMMAD AL-ANDUNISIY, Abu"; a.k.a. "MUHAMMAD AL-INDONESI, Abu"; a.k.a. "MUHAMMAD AL-INDUNISI, Abu"; a.k.a. "SHABRINA, Abu"), Raqqa, Syria; Al-Shadadi, Hasaka Province, Syria; DOB 23 Jul 1984; POB Bogor, Indonesia; nationality Indonesia; Gender Male; Passport A8329173 (Indonesia); Ustad (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

Dated: January 10, 2017.

**John E. Smith,**

*Acting Director, Office of Foreign Assets Control.*

[FR Doc. 2017-00761 Filed 1-13-17; 8:45 am]

**BILLING CODE 4810-AL-P**

## DEPARTMENT OF VETERANS AFFAIRS

### Loan Guaranty: Specially Adapted Housing Assistive Technology Grant Program

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Department of Veterans Affairs (VA), is announcing the availability of funds for the Specially Adapted Housing Assistive Technology (SAHAT) Grant Program for fiscal year (FY) 2017. The objective of the grant is to encourage the development of new assistive technologies for specially adapted housing.

This Notice is intended to provide applicants with the information necessary to apply for the SAHAT Grant Program. Registration will be available at [www.Grants.gov](http://www.Grants.gov). VA strongly recommends referring to the Loan Guaranty—Specially Adapted Housing Assistive Technology Grant Program final rule (38 CFR 36.4412) in conjunction with this Notice. The registration process described within this Notice applies only to applicants who will register to submit project applications for FY 2017 SAHAT Grant Program funds.

**DATES:** Applications for the SAHAT Grant Program must be submitted via [www.Grants.gov](http://www.Grants.gov) by 11:59 p.m. Eastern Time on February 26, 2017. The SAHAT Grant Program application package for funding opportunity, VA-SAHAT-17-02, is available through [www.Grants.gov](http://www.Grants.gov) and is listed as VA-Specially Adapted Housing Assistive Technology Grant Program. Applications may not be sent by mail, email or facsimile. All application materials must be in a format compatible with the [www.Grants.gov](http://www.Grants.gov) application submission tool. Applications must arrive as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected. Technical assistance with the preparation of an initial SAHAT Grant Program application is available by contacting the program official listed below.

#### FOR FURTHER INFORMATION CONTACT:

Bryant Lacey (Program Manager), Specially Adapted Housing Program, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632-8955 (not a toll-free number).

*Dated:* January 17, 2017.

*Full Text of Announcement:* This Notice is divided into eight sections. Section I provides a summary of and

background information on the SAHAT Grant Program as well as the statutory authority, desired outcomes, funding priorities, definitions, and delegation of authority. Section II provides award information, funding availability, and the anticipated start date of the SAHAT Grant Program. Section III provides detailed information on eligibility and the threshold criteria for submitting an application. Section IV provides detailed application and submission information, including how to request an application, application content, and submission dates and times. Section V describes the review process, scoring criteria, and selection process. Section VI provides award administration information such as award notices and reporting requirements. Section VII provides agency contacts. Section VIII provides additional information related to the SAHAT Grant Program. This Notice includes citations from 38 CFR part 36, which applicants and stakeholders are expected to read to increase their knowledge and understanding of the SAHAT Grant Program.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Program Description**

###### *A. Summary*

Pursuant to the Veterans' Benefit Act of 2010, the Secretary of Veterans Affairs (Secretary), through the Loan Guaranty Service (LGY) of the Veterans Benefits Administration (VBA), is authorized to provide grants of financial assistance to develop new assistive technology. The objective of the grant, known as the Specially Adapted Housing Assistive Technology (SAHAT) Grant Program, is to encourage the development of new assistive technologies for adapted housing.

###### *B. Background*

LGY currently administers the Specially Adapted Housing (SAH) Program. Through this program, LGY provides funds to eligible veterans and servicemembers with certain service-connected disabilities to help purchase or construct an adapted home, or modify an existing home, to allow them to live more independently. Currently, most SAH adaptations involve structural modifications such as ramps, wider hallways and doorways, roll-in showers and other accessible bathroom features, etc. For more information about the SAH Program, please visit: <http://www.benefits.va.gov/homeloans/adaptedhousing.asp>.

VA acknowledges there are many emerging technologies that could improve home adaptations or otherwise

enhance a veteran's or servicemember's ability to live independently, such as voice-recognition and voice-command operations, living environment controls, and adaptive feeding equipment. Therefore, VA has defined "new assistive technology" as an advancement that the Secretary determines could aid or enhance the ability of a veteran or servicemember to live in an adapted home. SAHAT funding will support the creation of assistive technologies that veterans and servicemembers can use in order to facilitate optimal independence in their homes.

Please Note: SAHAT funding does not support the construction or modification of residential dwellings for accessibility. Veterans and servicemembers interested in receiving assistance to adapt a home are encouraged to review the following factsheet: <http://www.prosthetics.va.gov/factsheet/PSAS-FactSheet-Housing-Adaptation-Programs.pdf> to identify Home Adaptation programs offered by VA.

###### *C. Statutory Authority*

Public Law 111-275, the Veterans' Benefits Act of 2010 (the Act), was enacted on October 13, 2010. Section 203 of the Act amended chapter 21, title 38, United States Code (U.S.C.), to establish the SAHAT Grant Program. The Act authorized VA to provide grants of up to \$200,000 per fiscal year, through September 30, 2016, to a "person or entity" for the development of specially adapted housing assistive technologies limited to \$1 million, the aggregate amount of such grants VA may award in any fiscal year.

On September 29, 2016, Public Law 114-228, the Department of Veterans Affairs Expiring Authorities Act of 2016 was enacted. Title IV, Section 409 extended the authority for VA to provide grants in the manner listed above, through September 30, 2017.

Reference: 38 U.S.C. 2108 and 36 CFR 36.4412

###### *D. Desired Outcomes and Funding Priorities*

Grantees will be expected to leverage grant funds to develop new assistive technologies for specially adapted housing. Pursuant to 36 CFR 36.4412, the Secretary may establish scoring priorities based on the specific needs of veterans and servicemembers. For FY 2017, the Secretary has established innovation and unmet needs, as described in scoring criteria 1 and 2 contained in Section V(A) of this notice, as top priorities. Additional information regarding how these priorities will be scored is contained in Section V(A) of this notice.

###### *E. Definitions*

Definitions of terms used in the SAHAT Grant Program are found at 38 CFR 36.4412(b).

###### *F. Delegation of Authority*

Pursuant to 38 CFR 36.4412(i), each VA employee appointed to or lawfully fulfilling any of the following positions is hereby delegated authority, within the limitations and conditions prescribed by law, to exercise the powers and functions of the Secretary with respect to the SAHAT Grant Program authorized by 38 U.S.C. 2108:

1. Under Secretary for Benefits
2. Deputy Under Secretary for Economic Opportunity
3. Director, Loan Guaranty Service
4. Deputy Director, Loan Guaranty Service

##### **II. Award Information**

###### *A. Funding Availability*

The aggregate amount of assistance VA may award in any fiscal year is limited to \$1 million. This funding will be provided as an assistance agreement in the form of grants. The number of assistance agreements VA will fund as a result of this notice will be based on the quality of the technology grant applications received and the availability of funding. However, the maximum amount of assistance a technology grant applicant may receive in any fiscal year is limited to \$200,000.

###### *B. Additional Funding Information*

Funding for these projects is not guaranteed and is subject to the availability of funds and the evaluation of technology grant applications based on the criteria in this announcement. In appropriate circumstances, VA reserves the right to partially fund technology grant applications by funding discrete portions or phases of proposed projects. If VA decides to partially fund a technology grant application, it will do so in a manner that does not prejudice any application or affect the basis upon which the application, or portion thereof, was evaluated and selected for award, and therefore maintains the integrity of the competition and selection process. Award of funding through this competition is not a guarantee of future funding. The SAHAT Grant Program is administered annually and does not guarantee subsequent awards. Renewal grants to provide new assistive technology will not be considered under this announcement.

### C. Start and Close-Out Date

The anticipated start date of grants funded under this announcement is April 3, 2017. Grant projects must be closed out by September 30, 2018.

## III. Eligibility Information

### A. Eligible Applicants

As authorized by 38 U.S.C. 2108, the Secretary may provide a grant to a "person or entity" for the development of specially adapted housing assistive technologies. In order to foster competition and best serve the needs of veterans and servicemembers, VA is placing no restrictions on the types of eligible entities, except as noted in Section III(C) of this notice.

### B. Cost Sharing or Matching

There is no cost sharing, matching, or cost participation for the SAHAT Grant Program. However, leveraged resources will be considered as an evaluation criterion during the application review process (see scoring criterion 6 in Section V of this announcement). Leveraged resources are not included in the approved budget (outlined in the Standard Form 424A—BUDGET INFORMATION—Non-Construction Programs) for the project and need not be an eligible and allowable cost under the grant. Any form of proposed leveraging that is evaluated under Section V scoring criteria must be included in the application and the application must describe how the technology grant applicant will obtain the leveraged resources and what role VA funding will play in the overall project.

### C. Threshold Criteria

As stated in Section III(A), VA is placing no restrictions on the types of eligible entities. However, all technology grant applicants and applications must meet the threshold criteria set forth below. Failure to meet any of the following threshold criteria in the application will result in the automatic disqualification for funding consideration. Ineligible participants will be notified within 30 days of the finding of disqualification for award consideration based on the following threshold criteria:

1. Projects funded under this notice must involve new assistive technologies that the Secretary determines could aid or enhance the ability of a veteran or servicemember to live in an adapted home.
2. Projects funded under this notice must not be used for the completion of work which was to have been completed under a prior grant.

3. Applications in which the technology grant applicant is requesting assistance funds in excess of \$200,000 will not be reviewed.

4. Applications that do not comply with the application and submission information provided in Section IV of this notice will be rejected.

5. Applications submitted via mail, email, or facsimile will not be reviewed.

6. Applications must be received through *www.Grants.gov*, as specified in Section IV of this announcement, on or before the application deadline, February 26, 2017. Applications received through *www.Grants.gov* after the application deadline will be considered late and will not be reviewed.

7. Technology grant applicants that have an outstanding obligation to the Federal Government that is in arrears or have an overdue or unsatisfactory response to an audit will be deemed ineligible.

8. Technology grant applicants in default by failing to meet the requirements for any previous Federal assistance will be deemed ineligible.

9. Applications submitted by entities deemed ineligible will not be reviewed.

10. Applications with project dates that extend past September 30, 2018, will not be reviewed.

All technology grant recipients, including individuals and entities formed as for-profit entities, will be subject to the rules on Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and other Non-profit Organizations, as found at 2 CFR part 200. Where the Secretary determines that 2 CFR part 200 is not applicable or where the Secretary determines that additional requirements are necessary due to the uniqueness of a situation, the Secretary will apply the same standard applicable to exceptions under 2 CFR 200.102.

## IV. Application and Submission Information

### A. Address To Request Application Package

Technology grant applicants may download the application package from *www.Grants.gov*. Questions regarding the application process should be referred to the program official: Bryant Lacey (Program Manager), Specially Adapted Housing Program, *Bryant.Lacey@va.gov*, (202) 632-8955 (This is not a toll-free number.).

### B. Content and Form of Application Submission

The SAHAT Grant Program application package provided at

*www.Grants.gov* (Funding Opportunity Number: VA-SAHAT-17-02) contains electronic versions of the application forms that are required. Additional attachments to satisfy the required application information may be provided; however, letters of support included with the application will not be reviewed. All technology grant applications must consist of the following:

1. *Standard Forms (SF) 424, 424A and 424B*: The SF-424, SF-424A, and SF-424B require general information about the applicant and proposed project. The project budget should be described in SF-424A. Please do not include leveraged resources in SF-424A.

2. *VA Form 26-0967*: Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion.

3. *VA Form 26-0967a*: Scoring Criteria for SAH Assistive Technology Grants.

4. *Applications*: In addition to the forms listed above, each technology grant application must include the following information:

a. A project description, including the goals and objectives of the project, what the project is expected to achieve, and how the project will benefit veterans and servicemembers.

b. An estimated schedule including the length of time (not to extend past September 30, 2018) needed to accomplish tasks and objectives for the project.

c. A description of what the project proposes to demonstrate and how this new technology will aid or enhance the ability of veterans and servicemembers to live in an adapted home. The following link has additional information regarding adapted homes: <http://www.benefits.va.gov/homeloans/adaptedhousing.asp>.

d. Each technology grant applicant is responsible for ensuring that the application addresses each of the scoring criteria listed in Section V(A) of this notice.

### C. Dun and Bradstreet Universal Numbering System (DUNS) and System for Award Management (SAM)

Each technology grant applicant, unless the applicant is an individual or Federal awarding agency that is excepted from these requirements under 2 CFR 25.110(b) or (c), or has an exception approved by VA under 2 CFR 25.110(d), is required to:

1. Be registered in SAM prior to submitting an application;
2. Provide a valid DUNS number in the application; and
3. Continue to maintain an active SAM registration with current

information at all times during which the technology grant applicant has an active Federal award or an application under consideration by VA.

VA will not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if the applicant has not fully complied with the requirements by the time VA is ready to make an award, VA will determine the applicant is not qualified to receive a Federal award and will use this determination as a basis for making the award to another applicant.

#### *D. Submission Dates and Times*

Applications for the SAHAT Grant Program must be submitted via [www.Grants.gov](http://www.Grants.gov) to be transmitted to VA by 11:59 p.m. Eastern Time on February 26, 2017. Submissions received after this application deadline will be considered late and will not be reviewed or considered. Submissions via email, mail, or fax will not be accepted.

Applications submitted via [www.Grants.gov](http://www.Grants.gov) must be submitted by an individual registered with [www.Grants.gov](http://www.Grants.gov) and authorized to sign applications for Federal assistance. For more information and to complete the registration process, visit [www.Grants.gov](http://www.Grants.gov). Technology grant applicants are responsible for ensuring that the registration process does not hinder timely submission of the application.

It is the responsibility of grant applicants to ensure a complete application is submitted via [www.Grants.gov](http://www.Grants.gov). Applicants are encouraged to periodically review the "Version History Tab" of the funding opportunity announcement in [www.Grants.gov](http://www.Grants.gov) to identify if any modifications have been made to the funding announcement and/or opportunity package. Upon initial download of the funding opportunity package, applicants will be asked to provide an email address that will allow [www.Grants.gov](http://www.Grants.gov) to send you an email message in the event this funding opportunity package is changed and/or republished on [www.Grants.gov](http://www.Grants.gov) prior to the posted closing date.

#### *E. Confidential Business Information*

It is recommended that confidential business information (CBI) not be included in your application. However, if CBI is included in your application, it will be handled by VA in accordance with 2 CFR 200. Applicants must clearly indicate which portion(s) of their application they are claiming as CBI. VA will evaluate such claims in accordance

with 2 CFR 200. If no claim is made, VA is not required to make an inquiry of the applicant. If CBI is included, please provide as much detail as possible to ensure a comprehensive review of the application can be completed.

#### *F. Intergovernmental Review*

This section is not applicable to the SAHAT Grant Program.

#### *G. Funding Restrictions*

The SAHAT Grant Program does not allow reimbursement of pre-award costs.

### **V. Application Review Information**

Each eligible proposal (based on the Section III threshold eligibility review) will be evaluated according to the criteria established by the Secretary and provided as described below in Section A.

#### *A. Scoring Criteria*

The Secretary will score technology grant applications based on the scoring criteria listed below. As indicated in Section I of this notice, the Secretary is placing the greatest emphasis on criteria 1 and 2. The establishment of priorities does not establish new scoring criteria but is designed to assist technology grant applicants in understanding how scores will be weighted. Although there is not a cap on the maximum aggregate score possible, a technology grant application must receive a minimum aggregate score of 70. Instructions for completion of the scoring criteria are listed on VA Form 26-0967a. This form is included in the application package materials on [www.Grants.gov](http://www.Grants.gov). The scoring criteria and maximum points are as follows:

1. A description of how the new assistive technology is innovative (up to 50 points);
2. An explanation of how the new assistive technology will meet a specific, unmet need among eligible individuals (up to 50 points);
3. An explanation of how the new assistive technology is specifically designed to promote the ability of eligible individuals to live more independently (up to 30 points);
4. A description of the new assistive technology's concept, size, and scope (up to 30 points);
5. An implementation plan with major milestones for bringing the new assistive technology into production and to the market. Such milestones must be meaningful and achievable within a specific timeframe (up to 30 points); and
6. An explanation of what uniquely positions the technology grant applicant

in the marketplace. This can include a focus on characteristics such as the economic reliability of the technology grant applicant, the technology grant applicant's status as a minority or Veteran-owned business, or other characteristics that the technology grant applicant wants to include to show how it will help protect the interests of, or further the mission of, VA and the program (up to 20 points).

#### *B. Review and Selection Process*

Eligible applications will be evaluated by a five-person review panel comprised of VA employees. The review panel will score applications using the scoring criteria provided in Section V(A), with the greatest emphasis being placed on scoring criteria 1 and 2. The review panel will then rank those applications that receive a minimum aggregate score of 70 in order from highest to lowest. The delegated official will select the highest ranked application(s) based on, and subject to, the availability of funds.

### **VI. Award Administration Information**

#### *A. Award Notices*

Although subject to change, the SAHAT Grant Program Office expects to announce grant recipients by April 1, 2017. Prior to executing any funding agreement, VA will contact successful applicants, make known the amount of proposed funding, and verify the applicant's desire to receive the funding. Any communication between the SAHAT Grant Program Office and successful applicants prior to the issuance of an award notice is not authorization to begin project activities. Once VA verifies that the grant applicant is still seeking funding, VA will issue a signed and dated award notice. The award notice will be sent by U.S. Mail to the organization listed on the SF-424.

All applicants will be notified by letter, sent by U.S. Mail to the address listed on the SF-424.

#### *B. Administrative and National Policy Requirements*

This section is not applicable to the SAHAT Grant Program.

#### *C. Reporting*

VA places great emphasis on the responsibility and accountability of grantees. Grantees must agree to cooperate with any Federal evaluation of the program and provide the following:

1. *Quarterly Progress Reports:* These reports will be submitted electronically and outline how grant funds were used, describe program progress, and describe any barriers and measurable outcomes.

Grantees will utilize the Research Performance Progress Report for quarterly reporting purposes.

2. *Quarterly Financial Reports:* These reports will be submitted electronically using the SF-425—Federal Financial Report.

3. *Grantee Closeout Report:* This final report will be submitted electronically and will detail the assistive technology developed. The Closeout Report must be submitted to the SAHAT Grant Program Office not later than 11:59 p.m. Eastern Time, September 30, 2018.

#### *D. Disputes*

Competition-related disputes associated with this announcement will be resolved in accordance with 2 CFR 200, *et seq.*

#### **VII. Agency Contact(s)**

For additional general information about this announcement contact the program official: Bryant Lacey (Program Manager), Specially Adapted Housing Program, [Bryant.Lacey@va.gov](mailto:Bryant.Lacey@va.gov), (202) 632-8955 (This is not a toll-free number.).

If mailing correspondence, other than application material, please send to: Loan Guaranty Service, VA Central Office, Attn: Bryant Lacey (262), 810 Vermont Avenue NW., Washington, DC 20420.

All correspondence with VA concerning this announcement should reference the funding opportunity title and funding opportunity number listed at the top of this solicitation. Once the announcement deadline has passed, VA staff may not discuss this competition with applicants until the application review process has been completed.

#### **VIII. Other Information**

38 U.S.C. 2108 authorizes VA to provide grants for the development of new assistive technologies through September 30, 2017. Additional information related to the SAH program administered by LGY is available at: <http://www.benefits.va.gov/homeloans/adaptedhousing.asp>.

The SAHAT Grant is not a veterans' benefit. As such, the decisions of the Secretary are final and not subject to the

same appeal rights as decisions related to veterans' benefits. The Secretary does not have a duty to assist technology grant applicants in obtaining a grant.

Grantees will receive payments electronically through the U.S. Department of Health and Human Services Payment Management System.

#### *Signing Authority*

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, approved this document on January 3, 2017, for publication.

Dated: January 11, 2017.

**Jeffrey Martin,**

*Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

[FR Doc. 2017-00797 Filed 1-13-17; 8:45 am]

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# FEDERAL REGISTER

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Part II

## Department of Health and Human Services

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Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, *et al.*

Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures; Final Rule



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, 423, and 478

[HHS–2016–79]

RIN 0991–AC02

### Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the procedures that the Department of Health and Human Services (HHS) follows at the Administrative Law Judge (ALJ) level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage (MA) and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. In addition, this final rule revises procedures that the Department of Health and Human Services follows at the Centers for Medicare & Medicaid Services (CMS) and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting the ALJ level.

**DATES:** These regulations are effective on March 20, 2017.

**FOR FURTHER INFORMATION CONTACT:** Joella Roland, (410) 786–7638 (for issues related to CMS appeals policies and reopening policies).

Jason Green, (571) 777–2723 (for issues related to Administrative Law Judge appeals policies).

Angela Roach, (202) 565–0132 (for issues related to Council appeals policies).

### SUPPLEMENTARY INFORMATION:

#### Abbreviations

Because we refer to a number of terms by abbreviation or a shortened form in this proposed rule, we are listing these abbreviations and shortened forms, and their corresponding terms in alphabetical order below:

AASIS—ALJ Appeal Status Information System

Act—Social Security Act

ALJ—Administrative Law Judge

APA—Administrative Procedure Act

BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)

CMS—Centers for Medicare & Medicaid Services

Council—Medicare Appeals Council

DAB—Departmental Appeals Board

DME—Durable Medical Equipment

EAJR—Expedited Access to Judicial Review

HHS—U.S. Department of Health and Human Services

IRE—Independent Review Entity

IRMAA—Income Related Monthly

Adjustment Amount

MA—Medicare Advantage

MAO—Medicare Advantage Organization

MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)

OCPM—OMHA Case Processing Manual

OIG—HHS Office of Inspector General

OMHA—Office of Medicare Hearings and Appeals

QIC—Qualified Independent Contractor

QIO—Quality Improvement Organization

SSA—Social Security Administration

VTC—Video-teleconferencing

### Section 1557 of the Affordable Care Act

Independent of the standards in this final rule, the Department commits to complying with section 1557 of the Affordable Care Act, Pub. L. 111–148, 124 Stat. 470 (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. HHS issued a final rule to implement section 1557, *Nondiscrimination in Health Programs and Activities*, on May 18, 2016. 81 FR 31376. The final rule applies, in part, to health programs and activities administered by the Department.

### Table of Contents

#### I. Background

A. Overview of the Appeals Process

B. Recent Workload Challenges

#### II. Summary of the Proposed Provisions and Response to Comments on the July 5, 2016, Proposed Rule

A. General Provisions of the Proposed Regulations

1. Precedential Final Decisions of the Secretary

2. Attorney Adjudicators

3. Application of 405 Rules to Other Parts

4. OMHA References

5. Medicare Appeals Council References

B. Specific Provisions of Part 405, Subpart I and Part 423, Subparts M and U

1. Overview

2. General Provisions, Reconsiderations, Reopenings, and Expedited Access to Judicial Review

a. Part 423, Subpart M General Provisions (§ 423.562)

b. Part 423, Subpart U Title and Scope (§ 423.1968)

c. Medicare Initial Determinations, Redeterminations and Appeals General Description (§ 405.904)

d. Parties to the Initial Determinations, Redeterminations, Reconsiderations Proceedings on a Request for Hearing, and Council Review (§ 405.906)

e. Medicaid State Agencies (§ 405.908)

f. Appointed Representatives (§ 405.910)

g. Actions That Are Not Initial Determinations (§ 405.926)

h. Notice of A Redetermination (§ 405.956)

i. Time Frame for Making a Reconsideration Following a Contractor Redetermination, Withdrawal or Dismissal of a Request for a Reconsideration, and Reconsideration (§§ 405.970, 405.972, and 405.974)

j. Notice of Reconsideration (§ 405.976)

k. Effect of a Reconsideration (§ 405.978)

l. Reopenings (§§ 405.980, 405.982, 405.984, 423.1978, 423.1980, 423.1982, and 423.1984)

m. Expedited Access to Judicial Review (§§ 405.990 and 423.1990)

#### 3. ALJ Hearings

a. Hearing Before an ALJ and Decision by an ALJ and Attorney Adjudicator: General Rule (§§ 405.1000 and 423.2000)

b. Right to an ALJ Hearing (§§ 405.1002 and 423.2002)

c. Right to a Review of QIC or IRE Notice of Dismissal (§§ 405.1004 and 423.2004)

d. Amount in Controversy Required for an ALJ Hearing (§§ 405.1006 and 423.1970)

e. Parties to an ALJ Hearing (§§ 405.1008 and 423.2008)

f. CMS and CMS Contractors as Participants or Parties in the Adjudication Process (§§ 405.1010, 405.1012, and 423.2010)

i. Section 405.1010: When CMS or Its Contractors May Participate in the Proceedings on a Request for an ALJ Hearing

ii. Section 423.2010: When CMS, the IRE, or Part D Plan Sponsors May Participate in the Proceedings on a Request for an ALJ Hearing

iii. Section 405.1012: When CMS or Its Contractors May Be a Party to a Hearing

g. Request for an ALJ Hearing or Review of a QIC or an IRE Dismissal (§§ 405.1014, 423.1972 and 423.2014)

i. Requirements for a Request for Hearing or Review of a QIC or an IRE Dismissal

ii. Requests for Hearing Involving Statistical Sampling and Extrapolations

iii. Opportunity To Cure Defective Filings

iv. Where and When To File a Request for Hearing or Review of a QIC or an IRE Dismissal

v. Sending Copies of a Request for Hearing and Other Evidence to Other Parties to the Appeal

vi. Extending Time To File a Request for Hearing or Review of a QIC or an IRE Dismissal

h. Time Frames for Deciding an Appeal of a QIC or an IRE Reconsideration or an Escalated Request for a QIC Reconsideration, and Request for Council Review When an ALJ Does Not Issue a Decision Timely (§§ 405.1016, 405.1104 and 423.2016)

i. Section 405.1016: Time Frames for Deciding an Appeal of a QIC or an

- Escalated Request for a QIC Reconsideration
  - ii. Section 405.1104: Request for Council Review When an ALJ Does Not Issue a Decision Timely
  - iii. Section 423.2016: Time Frames for Deciding an Appeal of an IRE Reconsideration
    - i. Submitting Evidence (§§ 405.1018 and 423.2018)
    - j. Time and Place for a Hearing Before an ALJ (§§ 405.1020 and 423.2020)
    - k. Notice of a Hearing Before an ALJ and Objections to the Issues (§§ 405.1022, 405.1024, 423.2022, and 423.2024)
    - l. Disqualification of the ALJ or Attorney Adjudicator (§§ 405.1026 and 423.2026)
    - m. Review of Evidence Submitted by the Parties (§ 405.1028)
    - n. ALJ Hearing Procedures (§§ 405.1030 and 423.2030)
    - o. Issues Before an ALJ or Attorney Adjudicator (§§ 405.1032, 405.1064 and 423.2032)
    - p. Requesting Information From the QIC or IRE, and Remanding an Appeal (§§ 405.1034, 405.1056, 405.1058, 423.2034, 423.2056, and 423.2058)
    - q. Description of the ALJ Hearing Process and Discovery (§§ 405.1036, 405.1037, and 423.2036)
    - r. Deciding a Case Without a Hearing Before an ALJ (§§ 405.1038 and 423.2038)
    - s. Prehearing and Posthearing Conferences (§§ 405.1040 and 423.2040)
    - t. The Administrative Record (§§ 405.1042 and 423.2042)
    - u. Consolidated Proceedings (§§ 405.1044 and 423.2044)
    - v. Notice of Decision and Effect of an ALJ's or Attorney Adjudicator's Decision (§§ 405.1046, 405.1048, 423.2046, and 423.2048)
    - w. Removal of a Hearing Request From an ALJ to the Council (§§ 405.1050 and 423.2050)
    - x. Dismissal of a Request for Hearing or Request for Review and Effect of a Dismissal of a Request for Hearing or Request for Review (§§ 405.1052, 405.1054, 423.2052 and 423.2054)
  - 4. Applicability of Medicare Coverage Policies (§§ 405.1060, 405.1062, 405.1063, 423.2062, and 423.2063)
  - 5. Council Review and Judicial Review
    - a. Council Review: General (§§ 405.1100, 423.1974 and 423.2100)
    - b. Request for Council Review When ALJ Issues Decision or Dismissal (§§ 405.1102 and 423.2102)
    - c. Where a Request for Review or Escalation May Be Filed (§§ 405.1106 and 423.2106)
    - d. Council Actions When Request for Review or Escalation Is Filed (§§ 405.1108 and 423.2108)
    - e. Council Reviews on Its Own Motion (§§ 405.1110 and 423.2110)
    - f. Content of Request for Review (§§ 405.1112 and 423.2112)
    - g. Dismissal of Request for Review (§§ 405.1114 and 423.2114)
    - h. Effect of Dismissal of Request for Council Review or Request for Hearing (§§ 405.1116 and 423.2116)
  - i. Obtaining Evidence From the Council (§§ 405.1118 and 423.2118)
  - j. What Evidence May Be Submitted to the Council (§§ 405.1122 and 423.2122)
  - k. Case Remanded by the Council (§§ 405.1126 and 423.2126)
    - l. Action of the Council (§§ 405.1128 and 423.2128)
  - m. Request for Escalation to Federal Court (§ 405.1132)
  - n. Judicial Review (§§ 405.1136, 423.1976, and 423.2136)
  - o. Case Remanded by a Federal Court (§§ 405.1038 and 423.2138)
  - p. Council Review of ALJ decision in a Case Remanded by a Federal District Court (§§ 405.1140 and 423.2140)
- C. Specific Provisions of Part 405, Subpart J Expedited Reconsiderations
- D. Specific Provisions of Part 422, Subpart M
1. General Provisions (§ 422.562).
  2. Notice of Reconsidered Determination by the Independent Entity (§ 422.594).
  3. Request for an ALJ Hearing (§ 422.602).
  4. Medicare Appeals Council (Council) Review (§ 422.608).
  5. Judicial Review (§ 422.612)
  6. Reopening and Revising Determinations and Decisions (§ 422.616)
  7. How an MA Organization Must Effectuate Standard Reconsideration Determinations and Decisions, and Expedited Reconsidered Determinations (§§ 422.618 and 422.619)
  8. Requesting Immediate QIO Review of the Decision To Discharge From the Inpatient Hospital and Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§§ 422.622 and 422.626).
- E. Specific Provisions of Part 478, Subpart B
1. Applicability and Beneficiary's Right to a Hearing (§§ 478.14 and 478.40)
  2. Submitting a Request for a Hearing (§ 478.42)
  3. Determining the Amount in Controversy (§ 478.44)
  4. Medicare Appeals Council and Judicial Review (§ 478.46)
  5. Reopening and Revision of a Reconsidered Determination or a Decision (§ 478.48)
- F. Effective Date and Applicability of the Provisions of the Final Rule
- III. Comments Beyond the Scope of the Final Rule
- IV. Provisions of the Final Rule
- V. Collection of Information Requirements
- VI. Regulatory Impact Statement
- VII. Federal Analysis

## I. Background

### A. Overview of the Appeals Process

In accordance with provisions of sections 1155, 1852, 1860D–4, 1869, and 1876 of the Social Security Act (Act), and associated implementing regulations, there are multiple administrative appeal processes for Medicare fee-for-service (Part A and Part B) claim, entitlement and certain premium initial determinations; MA

(Part C) and other competitive health plan organization determinations; and Part D plan sponsor coverage determinations and certain premium determinations. The first, and in many instances a second, level of administrative appeal are administered by Medicare contractors, Part D plan sponsors, MA organizations or Medicare plans, or by the SSA. For example, under section 1869 of the Act, the Medicare claims appeal process involves redeterminations conducted by the Medicare Administrative Contractors (which are independent of the staff that made the initial determination) followed by reconsiderations conducted by Qualified Independent Contractors (QICs). However, all of the appeals discussed in this final rule can be appealed to the ALJs at the Office of Medicare Hearings and Appeals (OMHA) if the amount in controversy requirement and other requirements are met after these first and/or second levels of appeal.

OMHA, a staff division within the Office of the Secretary of HHS, administers the nationwide ALJ hearing program for Medicare claim, organization and coverage determination, and entitlement and certain premium appeals. If the amount in controversy and other filing requirements are met, a hearing before an ALJ is available following a Quality Improvement Organization (QIO) reconsidered determination under section 1155 of the Act; a Social Security Administration (SSA) or QIC reconsideration, or a request for QIC reconsideration for which a decision is not issued timely and a party requests escalation of the matter under section 1869(b)(1)(A) and (d) of the Act (Part A and Part B appeals); an Independent Review Entity (IRE) reconsideration or QIO reconsidered determination under sections 1876(c)(5)(B) or 1852(g)(5) of the Act (Part C and other managed health plan appeals); or an IRE reconsideration under section 1860D–4(h) of the Act (Part D appeals). In addition, under current regulations a review by an ALJ is available following a dismissal of a request for reconsideration, if the amount in controversy and other filing requirements are met.

OMHA provides Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as applicable plans, Medicare Advantage Organizations (MAOs), and Medicaid State agencies with a fair and impartial forum to address disagreements regarding: Medicare coverage and

payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors; and determinations related to Medicare beneficiary eligibility and entitlement, Part B late enrollment penalties, and income related monthly adjustment amounts (IRMAAs), which apply to Medicare Part B and Part D premiums, made by SSA. Further review of OMHA ALJ decisions, except decisions affirming a dismissal of a request for reconsideration, is available from the Medicare Appeals Council (Council) within the DAB, a staff division within the Office of the Secretary of HHS. Judicial review is then available for Council decisions in Federal courts, if the amount in controversy and other requirements are met.

OMHA ALJs began adjudicating appeals in July 2005, based on section 931 of the MMA, which required the transfer of responsibility for the ALJ hearing level of the Medicare claim and entitlement appeals process from SSA to HHS. New rules at 42 CFR part 405, subpart I and subpart J were also established to implement statutory changes to the Medicare fee-for-service (Part A and Part B) appeals process made by BIPA in 2000 and the MMA in 2003. Among other things, these new rules addressed appeals of reconsiderations made by QICs, which were created by BIPA for the Part A and Part B programs. These rules also apply to appeals of SSA reconsiderations. The statutory changes made by BIPA included a 90-day adjudication time frame for ALJs to adjudicate appeals of QIC reconsiderations beginning on the date that a request for an ALJ hearing is timely filed. The new part 405, subpart I rules were initially proposed in the November 15, 2002 **Federal Register** (67 FR 69312) (2002 Proposed Rule) to implement BIPA, and were subsequently implemented in an interim final rule with comment period, which also set forth new provisions to implement the MMA, in the March 8, 2005 **Federal Register** (70 FR 11420) (2005 Interim Final Rule). Correcting amendments to the 2005 Interim Final Rule were published in the June 30, 2005 **Federal Register** (70 FR 37700) (2005 Correcting Amendment I) and in the August 26, 2005 **Federal Register** (70 FR 50214) (2005 Correcting Amendment II), and the final rule was published in the December 9, 2009 **Federal Register** (74 FR 65296) (2009 Final Rule). Subsequent revisions to part 405, subpart I to implement the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act, Pub. L. 112–242) were published in the

February 27, 2015 **Federal Register** (80 FR 10611) (SMART Act Final Rule).

In addition to the part 405, subpart I rules, OMHA applies the rules at 42 CFR part 478, subpart B to individuals' appeals of QIO reconsidered determinations; part 422, subpart M to appeals of IRE reconsiderations or QIO reconsidered determinations under the MA (Part C) and other competitive health plan programs; and part 423, subpart U to appeals of IRE reconsiderations under the Medicare prescription drug (Part D) program.

### *B. Recent Workload Challenges*

In recent years, the Medicare appeals process has experienced an unprecedented and sustained increase in the number of appeals. At OMHA, for example, the number of requests for an ALJ hearing or review increased 1,222 percent, from fiscal year (FY) 2009 through FY 2014. We attribute the growth in appeals to: (1) The expanding Medicare beneficiary population<sup>1</sup> and utilization of services across that population; (2) enhanced monitoring of payment accuracy in the Medicare Part A and Part B (fee-for-service) programs; (3) growth in appeals from State Medicaid agencies<sup>2</sup> for beneficiaries dually enrolled in both Medicare and Medicaid; and (4) national implementation of the Medicare fee-for-service Recovery Audit program<sup>3</sup> in 2009. The increasing number of requests has strained OMHA's available resources and resulted in delays for appellants to obtain hearings and decisions.

Despite significant gains in OMHA ALJ productivity (in FY 2014, each OMHA ALJ issued, on average, a record 1,048 decisions and an additional 456 dismissals, compared to an average of 471 decisions and 80 dismissals per ALJ in 2009), and CMS and OMHA initiatives to address the increasing number of appeals,<sup>4</sup> the number of

requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals continue to exceed OMHA's capacity to adjudicate the requests. As of September 30, 2016, OMHA had over 650,000 pending appeals, while OMHA's adjudication capacity—based on a maximum sustainable capacity of 1,000 appeals per ALJ team—was approximately 92,000 appeals per year.

HHS has a three-prong approach to addressing the increasing number of appeals and the current backlog of claims waiting to be adjudicated at OMHA: (1) Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; (2) take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog; and (3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals. In this final rule, HHS is pursuing the three-prong approach by implementing rules that expand the pool of available OMHA adjudicators and improve the efficiency of the appeals process by streamlining the processes so less time is spent by adjudicators and parties on repetitive issues and procedural matters. In particular, we believe the proposals we are finalizing in section II.A.2 below to provide authority for attorneys to issue decisions when a decision can be issued without an ALJ hearing, dismissals when an appellant withdraws his or her request for an ALJ hearing, remnants as provided in §§ 405.1056 and 423.2056 as finalized in this rule or at the direction of the Council, and reviews of QIC and IRE dismissals, could redirect approximately 24,500 appeals per year to attorney adjudicators, who would be able to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload (see section VI below for more details regarding our estimate).

## **II. Summary of the Proposed Provisions and Responses to Comments on the July 5, 2016, Proposed Rule**

In the July 5, 2016 **Federal Register**, we published a proposed rule that would revise the procedures that the Department of Health and Human Services would follow at the ALJ level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in MA and other Medicare competitive health plans, and enrollees

<sup>1</sup> Enrollment in fee-for-service Medicare and MA and other competitive health plans increased from roughly 49 million beneficiaries and enrollees in 2011 to 55.5 million in 2015, while enrollment in Part D prescription drug plans and MA prescription drug plans increased from roughly 29.5 million in 2011 to 39.5 million in 2015 (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>).

<sup>2</sup> In FY 2009, OMHA received 230 requests for hearing filed by Medicaid State agencies, compared to nearly 25,000 in FY 2014.

<sup>3</sup> As of April 25, 2016, Recovery Audit-related appeals accounted for 31 percent of the pending appeals at OMHA. Based on trends in receipts at this time, we estimate that Recovery Audit related appeals currently constitute 20 percent of incoming appeals.

<sup>4</sup> CMS and OMHA initiatives include OMHA's Settlement Conference Facilitation and Statistical Sampling Initiative; and CMS's QIC formal

telephone discussion demonstration and increased use of prior authorization models for areas with high payment error rates.

in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. 81 FR 43790. In addition, we proposed to revise procedures that the Department of Health and Human Services would follow at the CMS and the Council levels of appeal for certain matters affecting the ALJ level. Discussed below are the comments to the July 5, 2016, proposed rule. We include a summary and explanation of each proposed regulatory provision, provide a summary of, and responses to, the comments received, and describe the changes, if any, to be made in finalizing the provision in this rulemaking.

We received 68 timely comments on the proposed rule from individuals, organizations representing providers and suppliers, beneficiary advocacy groups, law offices, health plans, CMS contractors, and others. Summaries of the public comments and our responses to those comments are set forth below.

#### A. General Provisions of the Proposed Regulations

##### 1. Precedential Final Decisions of the Secretary

Council decisions are binding on the parties to that particular appeal and are the final decisions of the Secretary from which judicial review may be sought under section 205(g) of the Act, in accordance with current §§ 405.1130, 422.612(b), 423.2130, and 478.46(b). As explained in the 2009 Final Rule (74 FR 65307 through 65308), “binding” indicates the parties are obligated to abide by the adjudicator’s action or decision unless further recourse is available and a party exercises that right. “Final” indicates that no further administrative review of the decision is available and judicial review may be immediately sought.

In 1999, the HHS Office of Inspector General (OIG) issued a report entitled “Medicare Administrative Appeals—ALJ Hearing Process” (OEI-04-97-00160) (Sept. 1999) (<http://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf>). In that report, the OIG noted that the DAB respondents voiced strong interest in having precedent setting authority in the Medicare administrative appeals process “to clean-up inconsistencies in the appeals process.” The OIG recommended that such a case precedent system be established.

Pursuant to section 931(a) of the MMA, HHS and SSA developed a plan for the transition of the ALJ hearing function for some types of Medicare appeals from SSA to HHS, and

addressed the feasibility of precedential authority of DAB decisions. See *Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals* (Mar. 2004) ([https://www.ssa.gov/legislation/medicare/medicare\\_appeal\\_transfer.pdf](https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf)). HHS determined that at that time, it was not feasible or appropriate to confer precedential authority on Council decisions, but indicated that it would reevaluate the merits of granting precedential authority to some or all Council decisions after the BIPA and MMA changes to the appeals process were fully implemented.

BIPA and MMA changes to the appeals process have now been fully implemented and we stated in the proposed rule that we believed it was appropriate to propose that select Council decisions be made precedential to increase consistency in decisions at all levels of appeal for appellants. We proposed in proposed § 401.109 to introduce precedential authority to the Medicare claim and entitlement appeals process under part 405, subpart I for Medicare fee-for-service (Part A and Part B) appeals; part 422, subpart M for appeals of organization determinations issued by MA and other competitive health plans (Part C appeals); part 423, subparts M and U for appeals of Part D prescription drug coverage determinations; and part 478, subpart B for appeals of certain QIO determinations. 81 FR 43790, 43792–43794. We proposed in § 401.109(a) that the Chair of the DAB would have authority to designate a final decision of the Secretary issued by the Council as precedential. In the proposed rule we stated that we believed this would provide appellants with a consistent body of final decisions of the Secretary upon which they could determine whether to seek appeals. We also stated it would assist appeal adjudicators at all levels of appeal by providing clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions. Further, we stated that in the limited circumstances in which a precedential decision would apply to a factual question, the decision would be binding where the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the Council issued the precedential final decision.

We stated in the proposed rule that it is appropriate for the DAB Chair to have the role of designating select Council decisions as precedential. The DAB Chair leads the DAB, which was established in 1973. The DAB has wide jurisdiction over disputes arising under

many HHS programs and components, and has issued precedential decisions for many years within several of its areas of jurisdiction. (Examples of DAB jurisdiction may be found at 45 CFR part 16, 42 CFR part 498, 42 CFR part 426, and on the DAB’s Web site at [www.hhs.gov/dab](http://www.hhs.gov/dab).) The Council has been housed within the DAB as an organization since 1995 and is itself also under the leadership of the DAB Chair. Thus, we stated that the DAB Chair brings both expertise in the Medicare claims appeals over which the Council has jurisdiction and experience from the DAB’s precedential cases to carrying out the role of designating Council decisions to be precedential. Moreover, we stated in the proposed rule that having the designation performed by the DAB Chair respects the continued independence of the Council as an adjudicative body by allowing the DAB to determine the effect of its own decisions. We also stated that limiting binding precedential effect to selected decisions provides the necessary discretion to designate as precedential those Council decisions in which a significant legal or factual issue was fully developed on the record and thoroughly analyzed. We further stated that designation might not be appropriate where an issue was mentioned in the decision as relevant but was not outcome determinative, and therefore may not have been as fully developed as is necessary for precedential decisions or where the issues addressed are not likely to have broad application beyond the particular case.

To help ensure appellants and other stakeholders are aware of Council decisions that are designated as precedential, we proposed in § 401.109(b) that notice of precedential decisions would be published in the **Federal Register**, and the decisions themselves would be made available to the public, with necessary precautions taken to remove personally identifiable information that cannot be disclosed without an individual’s consent. We stated that designated precedents would be posted on an accessible Web site maintained by HHS, and that decisions of the Council would bind all lower-level decision-makers from the date that the decisions are posted on the HHS Web site.

We proposed in § 401.109(c) to make these precedential decisions binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on SSA to the extent that SSA components adjudicate matters under the jurisdiction of CMS, in the same manner

as CMS Rulings under current § 401.108. That means the precedential decision would be binding on CMS and its contractors in making initial determinations, redeterminations, and reconsiderations, under part 405 subpart I, or equivalent determinations under parts 422 subpart M, 423 subparts M and U, and 478 subpart B; OMHA ALJs and, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 below), attorney adjudicators; the Council in its future decisions; and SSA to the extent that it adjudicates matters under the jurisdiction of CMS. Individual determinations and decisions by CMS contractors, OMHA ALJs, and the Council currently are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals. We did not propose to change the non-precedential status and non-binding effect on future initial determinations (and equivalent determinations) or claim appeals of any determinations or decisions except as to Council decisions designated as precedential by the DAB Chair.

We proposed to specify the scope of the precedential effect of a Council decision designated by the DAB Chair in § 401.109(d). Specifically, we proposed that the Council's legal analysis and interpretation of an authority or provision that is binding (see, for example §§ 405.1060 and 405.1063) or owed substantial deference (see, for example § 405.1062) would be binding in future determinations and appeals in which the same authority or provision is applied and is still in effect. However, we proposed that if CMS revises the authority or provision that is the subject of a precedential decision, the Council's legal analysis and interpretation would not be binding on claims or other disputes to which the revised authority or provision applies. For example, if a Council decision designated as precedential by the DAB Chair interprets a CMS manual instruction, that interpretation would be binding on pending and future appeals and initial determinations to which that manual instruction applies. However, CMS would be free to follow its normal internal process to revise the manual instruction at issue. Once the revised instruction is issued through the CMS process, the revised instruction would apply to making initial determinations on all claims thereafter. We stated that this would help ensure that CMS continues to have the ultimate authority to administer the Medicare program and promulgate regulations, and issue sub-

regulatory guidance and policies on Medicare coverage and payment.

If the decision is designated as precedential by the DAB Chair, we proposed in § 401.109(d) that the Council's findings of fact would be binding in future determinations and appeals that involve the same parties and evidence. For example, we stated in the proposed rule that if a precedential Council decision made findings of fact related to the issue of whether an item qualified as durable medical equipment (DME) and the same issue was in dispute in another appeal filed by the same party, and that party submitted the same evidence to support its assertion, the findings of fact in the precedential Council decision would be binding. However, we noted that many claim appeals turn on evidence of a beneficiary's condition or care at the time discrete items or services are furnished, and that therefore § 401.109, as proposed, is unlikely to apply to findings of fact in these appeals.

In addition, consistent with § 401.109, we proposed at § 405.968(b)(1) to add precedential decisions designated by the Chair of the Departmental Appeals Board (DAB) as an authority that is binding on the QIC. We also proposed at §§ 405.1063 and 423.2063, which currently cover the applicability of laws, regulations, and CMS Rulings, to add new paragraph (c) to the sections to provide that precedential decisions designated by the DAB Chair in accordance with § 401.109 are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and (in § 405.1063(c)) on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. Finally, we proposed to add precedential decisions to the titles of §§ 405.1063 and 423.2063 to reflect the additional topic covered by proposed paragraph (c).

We received forty-eight comments on this proposal. In two instances, the same commenter submitted the same comment twice, so there were forty-six distinct comments. Among those offering comments were providers and suppliers and organizations representing them, beneficiary advocacy groups, health plan providers and administrators, and individuals. Overall, the majority of commenters supported the proposal to designate certain Council cases as precedent, but some of them made requests for clarification or modification, which we address below. Twelve commenters either opposed the proposal or suggested that it be tabled for further

review. Some commenters did not take a clear position in favor of or against adoption of the proposal but offered various comments which we address below. Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Numerous commenters raised concerns regarding the lack of specific standards or criteria for selecting precedential decisions. One commenter suggested that the Council should adopt the standards currently used by federal circuit courts for designating precedential decisions. Two commenters requested clarity on the precedential effect of factual findings. One further opined that factual statements should never be given precedential effect because the Council is not a fact finding institution and because facts change over time. One commenter suggested that only decisions fully favorable to beneficiaries should be designated as precedential. Two commenters suggested that all Council decisions involving legal analysis or interpretations of authority should have precedential force, and others suggested that in addition to granting precedential authority to the Council, the rule should require MACs and QICs to treat prior ALJ decisions as precedential.

*Response:* We appreciate the commenters' concern about additional clarity as to how decisions will be selected to have precedential effect. As explained above, the purpose of § 401.109 is to increase predictability and consistency in decision-making throughout the appeals process, and to provide clear direction on repetitive legal and policy questions. We believe that designating certain decisions as precedential, and therefore binding on all lower levels of review, will help ensure that appellants and other stakeholders are provided a more predictable outcome at all stages of review. In addition, selecting certain decisions as precedential helps to ensure that similar cases receive consistent results.

We understand commenters' concern that stakeholders understand the considerations that will guide designation of precedential Council decisions. However, given that the variety of issues that may arise in the interpretation and application of Medicare law and policy is broad and changes rapidly, it is not practicable to articulate a comprehensive set of criteria that the DAB Chair must follow to determine which decisions are appropriate for such designation. We can, however, identify some factors that the DAB Chair may consider when

determining whether to designate a decision as precedential. The primary goal is to identify Council decisions involving issues of wide applicability where designation as precedent is likely to materially contribute to improving predictability and consistency in decisions prospectively. For example, decisions that address recurring legal issues, or interpret or clarify an existing law, CMS rule or policy, may be appropriately designated as precedential. In addition, the DAB Chair may also consider whether a decision has general application to a broad number of cases. Another factor the DAB Chair may consider is whether a decision analyzes or interprets a legal issue of general public interest. Before designating a decision as precedential, the DAB Chair may also take into consideration the state of the record developed at the lower levels of review. Records where the facts are fully developed and analyzed, or where legal arguments have been fully raised and argued are better candidates for precedential designation.

In response to the commenter's suggestion that the Council should adopt standards currently used by federal circuit courts for designating precedential decisions, we do not believe federal court standards provide the best model for criteria transferable to this internal agency administrative adjudication process. As a threshold matter, each federal circuit court establishes its own standards for designating precedent, so there is no uniform circuit court rule the Council can simply adopt. Moreover, there are substantial differences between the Medicare appeals system and the federal court system, and many factors considered by federal circuit courts in designating precedential decisions have no application in the Medicare appeals context. For example, many federal circuit courts will designate a decision as precedential if it establishes a rule of law within the circuit or creates a conflict with another circuit. Such criteria would not be applicable or helpful for the Council to consider because the Medicare appeals process is not divided into circuits. It is worth noting, however, that the factors identified in the preceding paragraph are similar to some of the factors federal circuit courts typically consider in designating precedent.

In regards to the effect of factual findings in precedential decisions, the Council's legal analysis and interpretation in a decision is applied in a specific factual context, as is also true with court decisions. That analysis and interpretation in a decision designated

as precedential must be applied by decision-makers at lower levels in future cases in which the same authority or provision applies and is still in effect. If the same authority or provision would not apply in a future case because the relevant facts are not the same, the precedential decision also would not be applicable in the future case. Moreover, if CMS issues new regulatory provisions or revised policies, a precedential decision analyzing and interpreting the prior regulations or policies may not apply on review of a coverage decision made under the new regulation or policy if the relevant content of the new regulation or policy is different from that interpreted in the precedential decision.

We understand the commenters may be concerned that proposed § 401.109(d)(2) authorizes the establishment of generally applicable "factual precedent." That proposed section, however, provides that factual findings in precedential decisions are binding only in future determinations and appeals involving the same parties, facts, and circumstances. The purpose of this provision is to discourage parties to a precedential decision from subsequently filing repetitive appeals involving the same facts in an effort to get a "second bite at the apple." It does not mean factual findings in a precedential decision would be binding in future claims involving different facts, parties, or circumstances.

We also disagree with the assertion that the Council is not a fact-finding institution. The Council's review is de novo and based on review of the entire administrative record as compiled through the OMHA level of appeal, including review of the hearing if one was conducted, as well as all additional admissible evidence and briefings submitted to the Council. Accordingly, Council decisions properly include factual findings and, as stated above, adjudicators will take into consideration relevant factual changes when determining whether a precedential decision should apply. We disagree with the suggestion that the DAB Chair should limit the pool of precedential decisions to only those that are favorable to the beneficiary. We do not believe the DAB should take into consideration to which party the decision was favorable when designating a decision as precedential. To do so would insert bias into the selection process, which goes against the DAB's mission to provide impartial and independent review. We also disagree with the suggestion that all Council decisions involving legal analysis or interpretations of authority

should have precedential effect. We understand the commenter's suggestion in this regard is to ensure consistency in the types of decisions that are designated as precedential. However, many Council decisions turn on the resolution of specific disputes of fact or on issues too unusual to have applicability or usefulness in other cases. As such, in those instances, the legal analyses or interpretations will not have widespread applicability or usefulness. We also decline to require MACs and QICs to treat prior ALJ decisions as precedential. Although there are limited circumstances where an ALJ decision may become a final decision, it is the role of the Council to issue final decisions on behalf of the Secretary. Those decisions of the Council designated as precedent will be binding on cases to which they are applicable at all lower levels of the agency adjudication process nationwide. We do not believe it would be appropriate for the decision of a single ALJ to establish precedent affecting parties nationwide without having been subject to review by the Council. Moreover, because ALJs would not be bound by each other's decisions, the decision of a MAC or QIC issued in compliance with one ALJ's decision might be reversed by a different ALJ. Therefore, making individual ALJ decisions precedential and binding on MACs and QICs would not necessarily serve the goal of increasing predictability and consistency.

Based on comments received and for the reasons we set forth, we are adding the following language to the final regulation at § 401.109(a) to include general criteria the DAB Chair may consider when selecting a Council decision as precedential, "In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest."

*Comment:* Several commenters questioned the provision granting the DAB Chair sole authority to designate decisions as precedential, or suggested that the designation process should include input from other sources, including providers, contractors, stakeholders, CMS, and OMHA. One commenter expressed concern that the DAB Chair as an agency employee may be biased against appellants. Other commenters felt the rule should provide a mechanism for appellants, advocates, and stakeholders to request that specific decisions be deemed precedential. In a

similar vein, some commenters felt that the rule should include procedures for challenging and overturning precedent. Some commenters suggested that these procedures should include granting appellants the right to seek judicial review after a decision is deemed precedential. A few commenters expressed concern that the rule contains no time frames for designating and applying precedential decisions.

*Response:* We disagree that it is inappropriate for the DAB Chair to have the sole authority to designate certain Council decisions as precedential. The Council is an adjudicatory and deliberative body comprised of the DAB Chair, Administrative Appeals Judges and Appeals Officers and is independent of the agency's operating divisions. To involve others, whether components of the agency or outside parties, in the designation process would undermine the independence of the Council. Any influence on the Council's legal interpretation or analysis outside the record and arguments developed within the scope of a case is inappropriate. Moreover, the DAB Chair, as a member of the Council, has the expertise and experience to determine which decisions should be designated as precedential because they will provide improved predictability and consistency across future cases. We also note here the designation of a decision as precedential does not create a new law or policy. By designating decisions as precedential, the DAB Chair is merely providing for consistent legal interpretation and analysis of CMS's existing laws, rule and policies. The contention that the DAB Chair as an "agency employee" may create a body of law that is more favorable to HHS is unsupported. The mission of the DAB is to provide impartial, independent review of disputed decisions in a wide range of HHS programs under more than 60 statutory provisions. The DAB Chair will continue to advance that mission when designating precedential Council decisions.

To the extent that appellants or CMS or its contractors believe that a case may result in a decision that should be considered precedential, then the parties are free to argue so in their appeal requests or own motion referrals. In addition, the Council routinely permits parties to file briefs and other written statements pursuant to 42 CFR 405.1120, which constitutes an appropriate mechanism by which parties could argue the potential precedential status of a decision. Filing a brief in a case would also aid in the fuller development and analysis of legal issues, which may make the resulting

decision a better candidate for precedential designation.

The regulations provide recourse to those appellants who do not agree with a Council's decision—judicial review. Appellants who disagree with the Council's legal interpretation or analysis in a decision may appeal the decision to federal district court in accordance with § 405.1136, regardless of whether the decision is designated as precedential. CMS also has recourse if it disagrees with a precedential decision. If CMS disagrees with the Council's legal interpretation and analysis of CMS's policy or rule, then CMS may change the policy or rule, or issue a later clarification or ruling. Given these existing mechanisms by which parties may challenge decisions on the merits or by which CMS may prospectively change policies, we do not believe it is necessary to include appeal rights or other procedures specific to challenging the designation of particular decisions as precedential.

We also decline to specify a timeframe in which the DAB Chair must designate a decision as precedential because resource and procedural constraints may limit how quickly the designation process may be completed. We do anticipate, however, that the DAB Chair will generally make the designation within a reasonable amount of time after the issuance of the decision, though as noted below, the DAB Chair may choose to wait to designate certain decisions as precedent until the time to file a request for judicial review expires. We also expect publication of the decision in the **Federal Register** to be done around the same time as a precedential decision is identified on the HHS Web site in order to provide public notice.

*Comment:* We received several comments requesting clarification on the effects of Council decisions designated as precedential. Two commenters sought clarification as to how findings made in precedential decisions should be used in the context of Medicare Part C and D appeals, and asked whether MAOs and Part D plan sponsors will be held accountable to these findings from an oversight perspective. One commenter sought clarification as to whether the Council will designate as precedential decisions relating to pre-service and copayment issues. Other commenters requested clarification on the effect of federal district court decisions that reverse Council decisions designated as precedential. One commenter further opined that because of the possibility of precedential decisions being overturned on judicial review, it is inappropriate to

make Council decisions precedential. A few commenters also suggested that the rule should include procedures for reversing claim denials resulting from subsequently overturned precedent. One commenter requested clarification as to whether a party whose appeal is denied based on a precedential decision must proceed through the full appeals process prior to seeking judicial review of the denial.

*Response:* We understand the desire for clarification on the effects of precedential decisions. To the extent the commenters are seeking clarification as to whether Part C and D plans will be required to determine the applicability of precedential decisions when adjudicating future cases, we clarify that § 401.109, as finalized, applies to all Medicare parts. As previously stated, the legal analysis and interpretation of a Medicare authority or provision in a decision designated as precedential must be applied by decision-makers at lower levels in future cases in which the same authority or provision applies and is still in effect. If the commenters seek clarification on whether Part C and D plans will be subject to additional oversight by CMS related to the application of precedential decisions, after the rule is finalized CMS will evaluate the extent to which the application of precedential decisions will require modification to existing plan oversight processes. In regards to whether Council decisions related to pre-service and copayment issues will be designated as precedential, we have outlined the factors the DAB Chair may consider when designating a precedential decision in the final regulation at § 401.109(a). With regard to the effect of a federal court decision that reverses a particular Council decision designated as precedential, the individual case would no longer be binding on the parties and would no longer serve as precedent. In order to ensure that this situation rarely arises, however, the DAB Chair may choose to wait to designate certain decisions as precedent until the time for appeal expires or until a federal court renders a final, unreviewable, decision on judicial review. Although we recognize the possibility that a Council decision designated as precedential may later be reversed, we do not agree that it is therefore inappropriate to designate certain decisions as precedential. The proposed structure is similar to the federal court system, where a federal circuit court's decision may be given precedential effect even though it ultimately may be reversed by the United States Supreme Court.



We also recognize the possibility that an appellant may seek judicial review of a later case applying the precedential decision. If a federal court reverses a later case applying a precedential Council decision, then the effect of the court's ruling on the original precedential decision will depend on many factors, including the court's basis for reversal, whether the court remands to the Council, whether the court's decision itself is non-precedential or non-published, and whether other federal courts have issued conflicting decisions. For example, a finding by the court that the precedent was misapplied to the later case might have a different impact than a finding that the rationale underlying the precedent was erroneous. Due to the many different possibilities, we do not believe we can address in advance the possible effects of federal court decisions on later cases applying precedential Council decisions.

For the same reasons, we also do not find it appropriate to create new procedures for reversing claim denials resulting from subsequently overturned precedent. We do note, however, that the existing appeals process permits some of the relief sought. If a party believes that a denial is based on overturned precedent, then it is free to appeal the denial and make that argument before the adjudicator.

If a party believes that its claim has been inappropriately denied because of the application of a precedential decision, the party must still exhaust the administrative appeals process as statutorily required under sections 1869 and 205 of the Act. We are without authority in this rulemaking to waive statutory requirements.

*Comment:* Some commenters expressed concerns that the proposal undermines ALJ independence and one commenter expressed concern that granting precedential authority to the Council will impose greater limits on the scope of ALJ reviews than currently exist.

*Response:* We disagree that the proposed rule impedes ALJ independence. ALJs, as well as the Council, are required to apply the laws and regulations pertaining to the Medicare and Medicaid programs as well as CMS rulings published under the authority of the CMS Administrator, regardless of whether a decision is designated as precedential (see § 405.1063). Council decisions do not create new laws or policies, but instead interpret CMS's existing laws, regulations and rulings and determine how they apply to specified circumstances. An ALJ remains free to

determine whether and how the relevant authority as interpreted by the Council applies in the context of a specific case.

*Comment:* Many commenters voiced general support for the proposal, but indicated contractors, providers, and suppliers need to be adequately trained and educated regarding the proper application of precedential decisions. A few commenters suggested that MACs and QICs should be provided with summaries of each precedential decision explaining how the decision may be applied to future claims. A few commenters sought clarification as to whether precedential decisions will be treated as supplemental to CMS manuals and guidelines. A few commenters also requested that all OMHA and Council decisions be made publicly available, even if non-precedential. One commenter suggested that precedential decisions should be posted on the Council's Web site and should only apply to claims decided after the posting date.

*Response:* We thank the commenters for their support. As we stated in the proposed rule, in addition to publishing decisions designated as precedential in the **Federal Register**, precedential decisions will be posted on an accessible HHS Web site and a precedential decision would be binding from the date posted. As regards the request that all OMHA and Council decisions be made publicly available (even if not precedential), we note that implementing this suggestion to publish the high volume of decisions issued at both the OMHA and Council levels would require extensive additional resources.

We agree that it is important for CMS, its contractors, providers, beneficiaries and other stakeholders to be educated on the existence of precedential decisions and their effects on pending appeals. In order to promote consistency, CMS, OMHA and the Council have participated in joint training sessions for the past several years. We anticipate including training sessions on precedential decisions as an effective means of educating all levels of adjudicators. In addition, education sessions may also be appropriate during forums where the public participates, such as the OMHA Appellant Forum. We find it inadvisable, however, to require the Council to provide to MACs and QICs summaries of each precedential decision discussing the precedential effect of a decision and how it should be applied to future cases. The precedent arises from the Council decision itself, and creating separate summaries risks possible ambiguity or

misunderstanding. While lower levels of review are bound by a legal interpretation or analysis, or certain factual findings, stated in a Council decision that has been designated as precedential, it is outside the Council's jurisdiction to instruct the review of lower-level adjudicators in cases not before the Council.

As we have noted, Council precedents do not create new law or policy and therefore do not "supplement" manuals or guidelines but may analyze, interpret, and apply them.

*Comment:* One commenter felt the proposal will not effectively reduce the backlog because it will take a significant amount of time to establish a meaningful body of precedential decisions.

*Response:* We acknowledge that it will take time to establish a body of precedential decisions addressing enough issues to meaningfully impact the backlog. Nevertheless, we believe that establishing precedential decisions will allow for more predictable and consistent outcomes at all levels of administrative review. Moreover, we anticipate that designating certain Council decisions as precedential will help parties better determine the likelihood of success on appeal and assist parties in making decisions regarding whether to pursue administrative appeal of their cases.

After review and consideration of the comments received, and for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.968, 405.1063, and 423.2063 as proposed without modification, and are finalizing § 401.109 with the following modification. As discussed above, we are adding the following language to § 401.109(a) to include the general factors the DAB Chair may consider when selecting a Council decision as precedential: "In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest."

## 2. Attorney Adjudicators

As described below, we proposed changes to provide authority for attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, to remand appeals as provided in §§ 405.1056 and 423.2056 or at the direction of the Council, and to conduct reviews of QIC

and IRE dismissals, 81 FR 43790, 43794–43795. Sections 1155, 1852(g)(5), 1860D–4(h), 1869(b)(1)(A), and 1876(c)(5)(B) of the Act provide a right to a hearing to the same extent as provided in section 205(b) by the HHS Secretary for certain appealable decisions by Medicare contractors or SSA, when the amount in controversy and other filing requirements are met. Hearings under these statutory provisions are conducted by OMHA ALJs with delegated authority from the HHS Secretary, in accordance with these sections and the APA.

Under current §§ 405.1038 and 423.2038, OMHA ALJs are also responsible for a portion of the appeals workload that does not require a hearing because a request for an ALJ hearing may also be addressed without conducting a hearing. For example, under §§ 405.1038 and 423.2038, if the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue, or if all parties agree in writing that they do not wish to appear before the ALJ at a hearing, the ALJ may issue a decision on the record without holding a hearing. Under current §§ 405.1052(a)(1) and 423.2052(a)(1), OMHA ALJs must also address a large number of requests to withdraw requests for ALJ hearings, which appellants often file pursuant to litigation settlements, law enforcement actions, and administrative agreements in which they agree to withdraw appeals and not seek further appeals of resolved claims. In addition, pursuant to §§ 405.1004 and 423.2004, OMHA ALJs review whether a QIC or IRE dismissal was in error. Under these sections, the ALJ reviews the dismissal, but no hearing is required. In FY 2015, OMHA ALJs addressed approximately 370 requests to review whether a QIC or IRE dismissal was in error. Also adding to the ALJs' workload are remands to Medicare contractors for information that can only be provided by CMS or its contractors under current §§ 405.1034(a) and 423.2034(a), and for further case development or information at the direction of the Council. Staff may identify the basis for these remands before an appeal is assigned to an ALJ and a remand order is prepared, but an ALJ must review the appeal and issue the remand order, taking the ALJ's time and attention away from hearings and making decisions on the merits of appeals.

Under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC under subsection (c). Subsection (c) of section 1869 of the Act involves the conduct of reconsiderations by QICs. We stated in

the proposed rule that we believe the statute does not require the action to be taken by an ALJ in cases where there is no QIC reconsideration (for example, where the QIC has issued a dismissal), or in cases of a remand or a withdrawal of a request for an ALJ hearing, and therefore the findings of fact and conclusions of law need not be rendered. As we stated in the proposed rule, ALJ hearings are ideally suited to obtain testimony and other evidence, and hear arguments related to the merits of a claim or other determination on appeal. ALJs are highly qualified to conduct those hearings and make findings of fact and conclusions of law to render a decision in the more complex records presented with a mix of documentary and testimonial evidence. However, we stated in the proposed rule that well-trained attorneys can perform a review of the administrative record and more efficiently draft the appropriate order for certain actions, such as issuing dismissals based on an appellant's withdrawal of a request for an ALJ hearing, remanding appeals for information or at the direction of the Council, and conducting reviews of QIC and IRE dismissals.

In addition, current §§ 405.1038 and 423.2038 provide mechanisms for deciding cases without an oral hearing, based on the written record. Cases may be decided without an oral hearing when the record supports a finding in favor of the appellant(s) on every issue; all of the parties have waived the oral hearing in writing; or the appellant lives outside of the United States and did not inform the ALJ that he or she wishes to appear, and there are no other parties who wish to appear. We stated in the proposed rule that, in these circumstances, the need for an experienced adjudicator knowledgeable in Medicare coverage and payment law continues, and well-trained attorneys can review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision in the appealed matter.

To enable OMHA to manage requests for ALJ hearings and requests for reviews of QIC and IRE dismissals in a more timely manner and increase service to appellants, while preserving access to a hearing before an ALJ in accordance with the statutes, we proposed to revise rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B, to provide authority that would allow attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a

hearing under the regulations, to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, and to remand appeals for information that can only be provided by CMS or its contractors or at the direction of the Council, as well as to conduct reviews of QIC and IRE dismissals. We also proposed to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. As we stated in the proposed rule, allowing attorney adjudicators to issue decisions, dismissals, and remands as described above, and to conduct reviews of QIC and IRE dismissals would expand the pool of OMHA adjudicators and allow ALJs to focus on cases going to a hearing, while still providing appellants with quality reviews and decisions, dismissals, and remands. In addition, we proposed that the rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council.

In addition, we noted that even if an attorney adjudicator was assigned to adjudicate a request for an ALJ hearing, that hearing request still could be reassigned to an ALJ for an oral hearing if the attorney adjudicator determined that a hearing could be necessary to render a decision. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with current §§ 405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal regardless of the waivers, pursuant to current §§ 405.1036(b)(3) or 423.2036(b)(3). We also noted that parties to a decision that is issued without an ALJ conducting an oral hearing pursuant to current §§ 405.1038(a) or 423.2038(a) (that is, the decision is favorable to the appellant on every issue and therefore may be issued based on the record alone) continue to have a right to a hearing and a right to examine the evidence on which the decision is based and may pursue that right by requesting a review of the decision by the Council, which can remand the case for an ALJ to

conduct a hearing and issue a new decision.

To implement this proposal, we proposed to revise provisions throughout part 405 subpart I, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections and in section III of the proposed rule. In addition, we proposed to define an attorney adjudicator in § 405.902, which provides definitions that apply to part 405 subpart I, as a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance. We also proposed to indicate in § 405.902 that the attorney adjudicator is authorized to take the actions provided for in subpart I on requests for ALJ hearing and requests for reviews of QIC dismissals. We stated that these revisions to § 405.902 would provide the public with an understanding of the attorney adjudicator's qualifications and scope of authority, and we also noted that attorney adjudicators would receive the same training as OMHA ALJs, which we note would focus on substantive areas of Medicare coverage and payment policy, as well as administrative procedures unrelated to the hearing components for which ALJs are exclusively responsible.

Provided below are summaries of the specific comments received and responses to these comments:

We received forty-seven comments on this proposal. A majority of the comments came from providers and suppliers, organizations representing providers and suppliers, beneficiary advocacy organizations, representatives, health plan providers, CMS contractors, and individuals. Twenty-nine of the commenters, mostly from the appellant community, generally supported or raised no objection to the proposal, but had requests for clarification, suggestions for modifications, and concerns or questions. Three commenters fully supported the proposal. Five commenters were equivocal. Three commenters generally supported the proposal, but opposed allowing attorney adjudicators to conduct reviews of QIC and IRE dismissals. Seven commenters opposed the proposal, including two comments from professional associations for ALJs.

*Comment:* A majority of commenters, mostly from organizations representing the appellant community, voiced broad support for the proposal, but a few commenters questioned whether the use of attorney adjudicators would significantly alleviate the backlog. One commenter questioned the utility of using attorney adjudicators given that all attorney adjudicators would be

afforded the same training as ALJs. The commenter suggested it seemed logical to simply hire more ALJs instead.

*Response:* We thank the commenters for their support. Requests for a hearing before an ALJ have increased dramatically in recent years and appeals pending at OMHA continue to exceed OMHA's capacity to adjudicate appeals within the time frames set forth in the statute and rules. The introduction of attorney adjudicators is one action that would help OMHA process cases more efficiently. Attorney adjudicators would allow OMHA to identify and adjudicate appeals that do not require a hearing as early in the administrative process as possible. The use of attorney adjudicators to adjudicate these appeals would reduce the wait time for appellants to receive decisions in cases in which no hearing is required or conducted. It would also help to address the volume of appeals OMHA continues to receive by channeling some of those appeals through a less costly adjudicator, which will allow OMHA to hire more adjudicators than the same resources would allow if allocated to hiring ALJs and support staff, while reserving ALJs and their support staff for appeals that require a hearing. We estimated in the proposed rule that, based on FY 2015 data, the proposal to expand the pool of adjudicators at OMHA could redirect approximately 23,650 appeals per year to attorney adjudicators, to process these appeals at a lower cost to the government than would be required if only ALJs were used to address the same workload. (Basing the estimates on FY 2016 data, we now estimate the impact to be approximately 24,500 appeals per year.) Thus, we believe the use of attorney adjudicators will help OMHA manage high receipt levels, and help alleviate the backlog by allowing OMHA to increase its overall adjudication capacity. OMHA has added as many ALJs and support staff as its current space and budget allow it to sustain. Additional ALJs and support staff will be hired to meet the need for adjudicators, as resources become available. However, the proposal would allow for OMHA to adjudicate more appeals using existing resources by providing for adjudication by attorney adjudicators of appeals that do not require a hearing before an ALJ.

*Comment:* Two commenters asked if attorney adjudicators would be doing the work that paralegals are already currently performing under the direction of an ALJ.

*Response:* Some OMHA paralegals do currently draft remands, dismissals, and decisions that will be made on the

record under the direction of an ALJ. However, we do not believe that is comparable to the work that will be performed by attorney adjudicators. Attorney adjudicators would be licensed attorneys and would have full responsibility for reviewing the record, assessing the pertinent facts in the record and identifying the relevant authorities, conducting the necessary analysis, and drafting and issuing the decision, remand, or dismissal under the attorney adjudicator's signature.

*Comment:* A few commenters believed that attorney adjudicators would not resolve the backlog because providers are unlikely to waive their right to a hearing if doing so would require them to forego the ability to present clinical information to either an ALJ or an attorney adjudicator.

*Response:* As discussed above and in the proposed rule, we believe attorney adjudicators will be an important new resource to help address the volume of appeals by increasing OMHA's adjudications capacity, which may help alleviate the backlog of pending appeals at OMHA. However, we have not suggested that the attorney adjudicator proposal will resolve the backlog; it is one of a number of administrative actions that we are undertaking to address the appeals workload and resulting backlog, and is in concert with other actions, such as requesting additional funding for the program. Further, we do not believe the proposal would require providers or other appellants to forego the ability to present clinical information to either an ALJ or attorney adjudicator. Although waiving the right to a hearing under current §§ 405.1038(b) and 423.2038(b) means an appellant and the other parties forgo the ability to present clinical information to an ALJ at a hearing, that does not preclude the appellant and other parties from presenting written information, including clinical information, for the ALJ to consider in issuing a decision based on the record alone, in accordance with current §§ 405.1018 and 423.2018. The same would be true under the regulations as finalized in this rule, except that an attorney adjudicator instead of an ALJ would issue the decision. The decision to waive the right to appear at a hearing before an ALJ is solely at the discretion of the appellant and, as finalized in this rule, the other parties who would be sent a notice of hearing if a hearing were to be scheduled. By waiving the right to appear at a hearing, the party would be requesting that the ALJ or attorney adjudicator issue a decision based on the written evidence in the record. In

addition, we note that parties also have the option to withdraw a waiver of the right to appear at the hearing any time before a notice of decision has been issued under §§ 405.1036(b)(2) and 423.2036(b)(2).

*Comment:* Many of the commenters who generally supported the proposal believed that OMHA should establish clear and specific guidelines for both the qualifications and the hiring of attorney adjudicators. Commenters suggested that attorney adjudicators should have at least one to three years of experience in Medicare coverage, payment, and appeals, obtained through work with a provider, OMHA, or CMS or its contractors. A few commenters recommended that OMHA hire its existing attorney advisors working under the direction of ALJs as attorney adjudicators.

*Response:* We thank the commenters for their support. We believe the definition we proposed in § 405.902 is sufficient to identify the requirement that attorney adjudicators be licensed attorneys, the knowledge that attorney adjudicators will possess, and their scope of authority. OMHA will identify desirable qualifications, including the specific knowledge, skills, and abilities necessary for an attorney adjudicator to be successful in the position, and human resource professionals will determine the specific guidelines for the qualifications and hiring for the position of attorney adjudicator in accordance with the Office of Personnel Management and HHS Departmental standards, after the effective date of the rule. The position description for the attorney adjudicator position and the job announcements will reflect these assessments and determinations. Further, although we may consider hiring existing OMHA attorney advisors as attorney adjudicators, we do not believe it would be appropriate to detail this type of information in the regulations at this time, or to make statements about what the qualifications may be before those delegated with authority to take human resource actions, such as the classification of positions and the determination of qualification standards, are consulted.

*Comment:* Most commenters emphasized the importance of training to help ensure attorney adjudicator decisions are consistent with Medicare law and guidance. One commenter from a professional association for ALJs indicated “with no definition of well trained or review criteria, an attorney adjudicator with little or no Medicare adjudicatory training or experience is more likely to issue a legally or factually incorrect decision than a well-seasoned

ALJ.” By contrast, several of the commenters who generally supported the proposal appreciated that, as discussed above and in section II.B of the proposed rule, attorney adjudicators would receive the same training as ALJs.

*Response:* We thank the commenters for their support, and disagree with the commenter who opined that in the absence of clearly defined training or review criteria, an attorney adjudicator with little or no Medicare adjudicatory training/experience would be more likely to issue a legally or factually incorrect decision than an ALJ. Section 405.902, as finalized in this rule, defines an attorney adjudicator as a licensed attorney employed by OMHA “with knowledge of Medicare coverage and payment laws and guidance.” As noted above (and discussed in section II.B of the proposed rule), attorney adjudicators would undergo the same training as new OMHA ALJs to help ensure that their decisions are consistent with Medicare law and guidance. In addition to hiring qualified adjudicators, OMHA ALJs and other legal staff, which would include attorney adjudicators, are required to attend continuing education and training programs to maintain familiarity with the most current Medicare law and guidance.

*Comment:* One commenter, on behalf of an association for ALJs, asked “what does guidance mean with respect to the Medicare Program, and if the attorney adjudicator receives guidance as to how to proceed with the claim from a supervisor at OMHA, an attorney adjudicator is not an independent decision-maker.”

*Response:* We believe this commenter misinterpreted the term “guidance” as set forth in the definition of attorney adjudicator in § 405.902. CMS and its contractors issue guidance that describe criteria for coverage and payment of items and services in the form local coverage determinations (LCDs), and CMS program memoranda and manual instructions. This is the guidance that is referenced in the definition of attorney adjudicator in § 405.902. Current § 405.1062(a) provides that ALJs are not bound by LCDs or CMS program guidance but must give substantial deference to these policies if they are applicable to a particular case. Section 405.1062(a), as finalized in this rule, extends the provision to require that attorney adjudicators, like ALJs, give the same substantial deference to these policies.

*Comment:* To guarantee an impartial and fair adjudication process, some commenters suggested OMHA should require attorney adjudicators to file a

financial disclosure report to ensure no financial conflicts of interest exist. Other commenters believed that the fact that attorney adjudicators would be rated and eligible for awards could create a conflict of interest because attorney adjudicators would have no protection from agency interference and may be assigned cases outside of rotation.

*Response:* As executive branch employees, all OMHA employees are subject to the Federal criminal conflict of interest statute at 18 U.S.C. 208, which prohibits a federal employee from participating in matters in which the employee, certain family members, or certain business associates have a financial interest, and to the Federal Employee Standards of Conduct at 5 CFR 2635, which provide general principles of ethical conduct and administer requirements regulating appearances of conflicts of interests, gifts, financial interests, impartiality in official duties, outside employment, and misuse of position. The regulations at 5 CFR 2634, implementing Federal statutes and administered by the Office of Government Ethics, set the guidelines for which employees are required to file financial disclosure reports subject to certification by an ethics official, in accordance with applicable statutes. HHS ethics officials, in consultation with the Office of Government Ethics, will determine which employees will be required to submit financial disclosures in accordance with the ethics regulations at 5 CFR 2634, which determines the content of such disclosures.

In addition, §§ 405.1026 and 423.2026, as finalized in this rule, serve as important safeguards in the administrative appeals process, and provide that an ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. This rule as finalized also provides a process that would allow a party to object to an assigned ALJ or attorney adjudicator. The objecting party would also have the opportunity to have the Council review the objections in cases where an adjudicator does not withdraw pursuant to §§ 405.1026 and 423.2026.

Under 5 U.S.C. 43 and 5 CFR 430.101, attorney adjudicators, as Federal employees, would be subject to the Performance Management Appraisal Program (PMAP), which provides for an annual performance appraisal of HHS Federal employees. ALJs are exempt from annual performance appraisals pursuant to 5 U.S.C. 4301(2)(D) and 5 CFR 430.202(b). However, the statutes

governing PMAPs do not provide an exclusion that would exempt attorney adjudicators from annual performance reviews. Annual performance reviews are an important tool for holding employees accountable and we believe that as stewards of taxpayer dollars, we are responsible for holding adjudicators accountable for minimal production levels and levels of quality in their work, through annual performance reviews or otherwise. However, in managing its obligation to administer PMAPs for all OMHA employees except ALJs, OMHA will take precautions to avoid performance criteria that would interfere with an attorney adjudicator's ability to independently make findings of fact based on the record, identify the applicable authorities, and issue a decision in accordance with those authorities, so as to afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs. Further, OMHA's business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. Based on the foregoing, we believe there will be protections in place to guarantee an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

*Comment:* Some commenters felt that attorney adjudicator decisions should be subject to oversight or a quality review process.

*Response:* We thank the commenters for their suggestion. In addition to reviews by the Council pursuant to a party's request for review or a referral by CMS as a check on individual decisions issued by ALJs and as proposed, attorney adjudicators, OMHA has a quality assurance program (QAP). The OMHA QAP involves a retrospective review of ALJ decisions and assists OMHA in identifying opportunities for training and policy development to increase decisional quality. The OMHA QAP will include attorney adjudicator decisions after the rule is implemented.

*Comment:* One commenter suggested OMHA should compile a yearly report to assess the impact attorney adjudicators have on the backlog, including the types of decisions issued and the percentage of dispositions that were in favor of the government.

*Response:* We thank the commenter for its suggestion. The OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)) currently contains summary tables that list overall disposition data and dispositions by ALJ. The data, which is organized by

fiscal year, includes the number of dispositions that were fully favorable, unfavorable, partially favorable, and dismissed. The disposition data will be expanded to include data for attorney adjudicators as they begin to decide appeals. We believe this data would assist OMHA and the public with assessing the impact of attorney adjudicators on the appeals workload.

*Comment:* One commenter indicated the proposed rule does not specify who would assign the cases to the ALJs and attorney adjudicators. Several commenters asked how cases will be assigned to attorney adjudicators and suggested OMHA must establish a well-defined process for assignment of cases to attorney adjudicators.

*Response:* OMHA's business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. More information on the appeal assignment process is available in the OMHA Case Processing Manual (OCPM), which is accessible to the public at the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)). If an appeal is initially assigned to an ALJ and the ALJ later determines it can be adjudicated by an attorney adjudicator, the appeal would be reassigned to an attorney adjudicator in the same manner as a new appeal assignment to an attorney adjudicator. Similarly, if an appeal is initially assigned to an attorney adjudicator and the attorney adjudicator later determines that only an ALJ can adjudicate the appeal, the appeal would be reassigned to an ALJ in the same manner as a new appeal assignment to an ALJ.

*Comment:* Several commenters supported the proposal to allow requests for hearings initially assigned to an attorney adjudicator to be reassigned to an ALJ for oral hearing if necessary in order to render a decision. However, commenters suggested OMHA establish clearer guidance and thresholds for reassignment and a timeline for an attorney adjudicator to reassign an appeal to an ALJ. One commenter indicated the proposal does not provide the regulatory text or authority for an attorney adjudicator to refer an appeal to an ALJ for hearing when the attorney adjudicator determines a hearing is required. A few commenters also indicated the proposal does not specify the procedure for reassignment of cases from an ALJ to an attorney adjudicator, where the ALJ has determined the disposition could be fully favorable, nor does the proposal require the ALJ to make a record of such a determination.

*Response:* We believe the threshold requirement of whether a hearing is necessary for a decision is clear in the statute and regulations. In addition, we decline to establish a time frame in the regulations for an attorney adjudicator to reassign a case to an ALJ, as this would be an internal process, and to do so would limit our flexibility to establish and change business processes through OMHA operational policies, which the Administrative Procedure Act (APA) permits OMHA to adopt without notice and comment rulemaking. We also do not believe that regulation text or authority is necessary for an attorney adjudicator to refer an appeal to an ALJ, as an attorney adjudicator would be referring the appeal to an ALJ because the attorney adjudicator believes that he or she does not have the authority to issue a decision in the appeal, for example, because the attorney adjudicator believes a hearing is necessary to decide the appeal.

Further, the procedure for reassignment of cases from an ALJ to an attorney adjudicator, for example, where the ALJ has determined the disposition could be fully favorable to the appellants on every issue based on the record and no other party is liable for the claims at issue, will also be established by OMHA operational policies, including the OCPM. However, we note that in the scenario presented in the comment, the ALJ would also have the authority to retain assignment of the appeal and issue a decision without conducting a hearing. In the event that an ALJ determines the disposition could be fully favorable to the appellants on every issue based on the record and no other party is liable for the claims at issue and the case is reassigned to an attorney adjudicator, the ALJ will not make a record of the determination because the attorney adjudicator will make an independent assessment and will not be bound by the ALJ's determination.

*Comment:* Several commenters asked whether OMHA would inform the parties to an appeal when the appeal is assigned to an attorney adjudicator.

*Response:* OMHA would continue its current practice of issuing a Notice of Assignment to appellants when a request is assigned, which includes the assigned adjudicator. Appellants and other parties can also obtain and track the status of a pending appeal, including its assigned adjudicator, by visiting OMHA's ALJ Appeal Status Information System (AASIS) page at: <http://aasis.omha.hhs.gov>.

*Comment:* Several commenters asked whether a party waiving the right to attend the hearing could choose a

decision by either an attorney adjudicator or an ALJ, and whether parties could object to the assignment. One commenter suggested modeling the attorney adjudicator process on existing Federal court process for the assignment of magistrates, where all parties would be given the option for their case to be assigned to an attorney adjudicator.

*Response:* Sections 405.1038 and 423.2038, as finalized in this rule, specifically indicate an ALJ or attorney adjudicator may decide a case on the record when an appeal can be decided without a hearing before an ALJ. These regulations, as finalized, serve as notice that waiving the right to appear at a hearing allows an attorney adjudicator to issue a decision, if a hearing is not necessary to decide the appeal (we note that a hearing may still be conducted by an ALJ if it is necessary to decide the appeal, even if one or more of the parties has waived their right to appear at the hearing). We believe that allowing the parties to choose whether an ALJ or attorney adjudicator will issue the decision when the right to appear at the hearing is waived, or to object if the appeal is assigned to an attorney adjudicator would negate some of the anticipated efficiencies of the proposal and provide the parties with undue influence over the adjudicator assigned to the appeal. However, we note that under §§ 405.1036(b)(2) and 423.2036(b)(2), as finalized in this rule, appellants and other parties may withdraw a waiver of the right to appear at the hearing at any time before a notice of decision has been issued. In addition, if an appellant has concerns about the individual assigned to the appeal having a conflict or bias, §§ 405.1026 and 423.2026, as finalized in this rule, can be used to request that the adjudicator withdraw from the appeal. We appreciate the suggestion to consider having an option for the parties to have their case assigned to an attorney adjudicator, similar to the Federal court process for some magistrate assignments. However, we do not believe that such an option would be appropriate for the administrative appeals addressed in this rule, because attorney adjudicators may only adjudicate appeals that do not require a hearing. A hearing may be necessary in some cases to decide the appeal, and in these cases, under section 1869 of the Act and the regulations finalized in this rule, only an ALJ may conduct a hearing.

*Comment:* Two commenters from professional associations for ALJs indicated that appellants, including self-represented appellants, may not know the difference between a decision by an

independent ALJ as compared to a decision issued by an attorney adjudicator. In the commenters' opinion, the record must clearly demonstrate a valid and informed waiver of the right to have a claim heard by an ALJ.

*Response:* We do not believe there will be a qualitative distinction in decisions issued by ALJs and attorney adjudicators, and both adjudicators will share a similar qualified decisional independence with respect to the decisions that they issue, as discussed further below. However, parties to Medicare claims and appeals are presumed to have knowledge of the published Medicare rules and guidance, regardless of whether they have representation. Therefore, we believe this final rule would serve as sufficient notice that by waiving the right to appear at a hearing, parties would be aware that the decision may be issued by either an ALJ or an attorney adjudicator, if no hearing is required to decide the appeal. However, we will review and revise appeal instructions, and online and other guidance available to appellants to highlight that if an oral hearing is waived, an attorney adjudicator may issue the decision. We will also review and revise current Form HHS-723 (Waiver of Right to an Administrative Law Judge (ALJ) Hearing) to clearly convey that a decision may be issued by an attorney adjudicator.

With regard to unrepresented beneficiaries and enrollees, we believe they represent the most vulnerable segment of the appellant population. However, it is rare that an unrepresented beneficiary waives the right to appear at the hearing. In practice, in the few instances when this does occur, OMHA reviews the stated reason for waiving the right to appear at the hearing and may contact the unrepresented beneficiary or enrollee to confirm that the waiver is knowingly made. We believe this process will help ensure that an unrepresented beneficiary or enrollee understands the implications of waiving his or her right to appear at the hearing and the record demonstrates that understanding. In addition, we are reviewing the current form for waiving the right to appear at a hearing (form HHS-723), to determine if revisions may be necessary so users will understand that by waiving the right to appear at the hearing, the waiving party would be aware that the decision may be issued by either an ALJ or an attorney adjudicator, if no hearing is required to decide the appeal.

*Comment:* Several commenters asked whether a party could appeal an

unfavorable decision by an attorney adjudicator to an ALJ. Several commenters believed OMHA should allow parties who disagree with the attorney adjudicator's decision to request an ALJ review the attorney adjudicator's decision and allow the ALJ to reissue an amended decision should the ALJ find the attorney adjudicator's decision to be deficient.

*Response:* A party would not have the right to appeal an unfavorable decision by an attorney adjudicator to an ALJ. All parties to an appeal would receive a written notice of decision issued by an attorney adjudicator. The notice of decision would provide instructions for requesting a review of the decision by the Council if a party disagrees with the decision. The rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council (see §§ 405.1102 and 405.1106, as finalized in this rule). Parties to a decision issued without an ALJ conducting an oral hearing pursuant to §§ 405.1038(a) or 423.2038(a) continue to have a right to a hearing and a right to examine the evidence on which the decision is based, and may pursue that right by requesting review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.

*Comment:* One commenter noted that the proposed rule is silent on the requirements for a timely request for ALJ hearing when a party to an appeal wishes to appeal a fully favorable on the record decision issued by an attorney adjudicator.

*Response:* As discussed above, parties to a decision issued without an ALJ conducting an oral hearing pursuant to §§ 405.1038(a) or 423.2038(a) continue to have a right to an ALJ hearing, and may pursue that right by appealing to the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. Sections 405.1102(a)(1) and 423.2102(a)(1), as finalized in this rule, provide that a party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a review of the decision by the Council by filing a written request for review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal. We believe §§ 405.1102(a)(1) and 423.2102, as finalized in this rule, provide the requirements for filing a timely request to appeal a decision issued by an attorney adjudicator, including a fully favorable decision issued by an attorney

adjudicator. In addition, we note that the notice of decision sent with an attorney adjudicator's decision will include instructions for filing a request for review with the Council, including the time frame in which the request for review must be filed.

*Comment:* One commenter stated "in any waiver to allow a decision by an attorney adjudicator, it must be clearly explained that by accepting such a decision, the beneficiary may be waiving his or her right to appeal the decision to the Federal district court as it will not have completed all administrative proceedings below."

*Response:* We disagree with the commenter's interpretation that a beneficiary would be waiving their right to appeal to Federal district court by waiving the right to an ALJ hearing. Section 405.904(a)(2), as finalized in this rule, states "If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met."

*Comment:* A few commenters, on behalf of Medicare contractors, asked whether attorney adjudicators could render summary decisions in favor of CMS Recovery Auditors or other interested contractors, or only in favor of the appellant. These commenters suggested summary decisions should be permitted to extend in both directions.

*Response:* We interpret the commenter's use of the term "summary decisions" to mean decisions that are issued on the record without a hearing before an ALJ, and we assume the commenters are asking whether attorney adjudicators could issue decisions on the record that are favorable to CMS and its contractors (or to CMS, the IRE, and/or the plan sponsor) pursuant to §§ 405.1038(a) and 423.2038(a). Sections 405.1038(a) and 423.2038(a), as finalized in this rule, clearly limit the ALJ's or attorney adjudicator's ability to issue decisions on the record to situations where the administrative record supports a finding fully in favor of the *appellant(s)* on every issue and no other party to the appeal is liable for claims at issue. Decisions that are favorable to CMS and its contractors (or to CMS, the IRE, and/or the plan

sponsor), are not fully favorable to the appellant(s) (because CMS and its contractors (or CMS, the IRE and/or the plan sponsor) are not appellants in a request for an ALJ hearing), and therefore, such a decision could not be issued on the record under §§ 405.1038(a) and 423.2038(a.), as finalized in this rule.

*Comment:* Many commenters suggested that OMHA establish a bright line rule and clear scope of an attorney adjudicator's authority. One commenter indicated "the number of cases that fall within [attorney adjudicators'] scope of authority is so limited, that their use will have no more than negligible impact on the processing of appeals."

*Response:* We believe the rule as finalized, clearly establishes the scope of an attorney adjudicator's authority. The scope and authority of an attorney adjudicator to issue decisions under the rule as finalized, is set forth in § 405.902, which states an "attorney adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals." Other rules in the subpart then describe when an attorney adjudicator may issue a decision, dismissal, or remand. As finalized in this rule, an attorney adjudicator may issue: (1) Decisions that can be issued without an ALJ conducting a hearing in accordance with §§ 405.1038 and 423.2038; (2) dismissals when an appellant withdraws his or her request for an ALJ hearing in accordance with §§ 405.1052 and 423.2052; (3) remands to the QIC, IRE, or other contractor, or the Part D plan sponsor, in accordance with §§ 405.1056 and 423.2056; and (4) reviews of QIC and IRE dismissals in accordance with §§ 405.1004 and 423.2004.

*Comment:* Some commenters supported allowing attorney adjudicators to issue dismissals when an appellant withdraws a request for hearing, remands for information that can only be supplied by CMS or contractors and, in certain instances, issue decisions that are fully favorable to the appellant, but the commenters opposed allowing attorney adjudicators to review a QIC or IRE dismissal, stating neither § 405.1004 nor § 423.2004 preclude a hearing being held for review of a QIC or IRE dismissal, respectively. These commenters suggested that the review of QIC and IRE dismissals "may sometimes require a hearing to determine findings of fact or conclusions of law."

*Response:* We recognize that current §§ 405.1004 and 423.2004 do not preclude conducting a hearing on a review or a QIC or IRE dismissal, and acknowledge review of QIC and IRE dismissals may sometimes require a hearing to determine findings of fact or conclusions of law. As discussed previously regarding the reassignment of cases from an attorney adjudicator to an ALJ, an attorney adjudicator may refer an appeal to an ALJ because the attorney adjudicator believes that he or she does not have the authority to issue a decision in the appeal, for example, because the attorney adjudicator believes a hearing is necessary to determine findings of fact or conclusions of law. These appeals will be reassigned to an ALJ to conduct a hearing. However, as discussed above and in section II.B of the proposed rule, although under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC, we believe that the statute does not require that the same action be taken by an ALJ in cases where there is no QIC reconsideration, for example, where the QIC has dismissed the request for reconsideration. In addition, we believe the determination whether a QIC or IRE dismissal was issued in error generally can be conducted on the record, given the limited scope of review, in the same manner as QICs review MAC dismissals of redetermination requests, and the Council reviews ALJ dismissals of requests for hearing. Moreover, we believe attorney adjudicators will be capable of reviewing the administrative record, identifying the issues related to the dismissal, and determining whether the QIC and IRE dismissal was issued in error.

*Comment:* One commenter requested that for cases where an attorney adjudicator finds the QIC or IRE dismissed an appeal in error, the appeal should be remanded to the QIC or IRE with the attorney adjudicator's reasoning for the decision and with instructions on how to proceed.

*Response:* Sections 405.1004(b) and 423.2004(b), as finalized in this rule, state if the ALJ or attorney adjudicator determines that the QIC's or IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC or IRE for a reconsideration in accordance with §§ 405.1056 and 423.2056. We expect that an ALJ's or attorney adjudicator's notice of remand will explain the ALJ's or attorney adjudicator's basis for vacating the QIC's or IRE's dismissal, and §§ 405.1056(d) and 423.2056(d), as finalized in this rule, state that the ALJ or attorney adjudicator will remand the case to the



QIC or IRE for a reconsideration, which we believe is the only required instruction.

*Comment:* A few commenters, including two professional associations for ALJs, opposed the attorney adjudicator proposal on the basis that the proposal is inconsistent with the APA or the Act and improperly delegates decision-making authority to individuals who are not appointed as ALJs. The commenters also argued provisions of the APA and the Act give ALJs judicial independence to render decisions, and attorney adjudicators do not have judicial independence to the same extent as ALJs.

*Response:* We disagree with the commenters and believe the proposal is fully consistent the APA and the Act. As a preliminary matter, we note that in interpreting the APA, courts have held that ALJs have “qualified decisional independence” in carrying out their adjudicative functions, rather than full “judicial independence.” According to the case law, the intent of the APA is that ALJs should decide each case based on the record evidence, free from any pressure from their employing agencies to reach a particular result in a particular case. This decisional independence is designed to help ensure impartial decision-making and to maintain public confidence in the essential fairness of the process. This decisional independence is, however, “qualified” because ALJs are still bound to follow the regulations and policies of their employing agency, and are also subject to direction designed to ensure efficient operation and service to the public. See *Butz v. Economou*, 438 U.S. 478, 513 (1978); *Abrams v. Social Security Administration*, 703 F. 3d 538, 545 (Fed. Cir. 2012); *Nash v. Bowen*, 869 F. 2d 675, 680 (2nd Cir. 1989), cert. denied, 493 U.S. 812 (1989); *Nash v. Califano*, 613 F. 2d 10, 15 (2nd Cir. 1980). In implementing this final rule, OMHA will afford attorney adjudicators the same level of qualified decisional independence. As discussed above, OMHA will take precautions to avoid performance criteria that would interfere with an attorney adjudicator’s ability to independently make findings of fact based on the record, identify the applicable authorities, and issue a decision in accordance with those authorities, so as to afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs. Further, OMHA’s business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. This

qualified decisional independence helps ensure an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

Sections 554 and 556 of the APA apply only to adjudications that are required by statute to be determined on the record after an opportunity for an agency hearing. In accordance with sections 1155, 1852(g)(5), 1860D–4(h), 1869(b)(1)(A), and 1876(c)(5)(B) of the Act and their implementing regulations (at 42 CFR part 405 subpart I, part 478 subpart B, part 422 subpart M, and part 423 subpart U), individuals dissatisfied with certain lower level appeal determinations are entitled to a hearing, subject to timely filing and amount in controversy limitations, to the same extent as is provided under section 205(b) of the Act. Reading these sections together, the Act directs the Secretary of Health and Human Services to provide an opportunity for a hearing regarding the right to Medicare benefits, which the Secretary has delegated to OMHA ALJs to conduct and render a decision. The rule, as finalized, is not inconsistent with the APA or the Act, but instead would augment this process by authorizing attorney adjudicators to make decisions in appeals when there is no requirement for a hearing, or in cases where parties waive the right to appear at a hearing before an ALJ and the hearing is not necessary to make a decision. The Act requires only that parties be given an opportunity for a hearing; no provision of the Act requires the Secretary to utilize an ALJ to issue a decision that does not require a hearing, for example, because the parties have waived their right to one or because no reconsideration has been issued.

Parties will continue to have an opportunity for a hearing where a reconsideration has been issued, the hearing request has been timely filed, and the amount remaining in controversy has been met. In that respect, the proposal, as finalized in this rule, does not change the process or the rights of the parties. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with §§ 405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal

regardless of the waivers, pursuant to §§ 405.1036(b)(3) or 423.2036(b)(3). In addition, parties to a decision issued without an ALJ conducting an oral hearing pursuant to §§ 405.1038(a) or 423.2038(a) continue to have a right to a hearing and a right to examine the evidence on which the decision is based, and may pursue that right by requesting review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. Under the rule we are finalizing, either an attorney adjudicator or an ALJ may issue a decision when no hearing is required before an ALJ, but if a hearing is to be held, the ALJ will conduct that hearing and issue the decision. We believe this process is fully in accord with the APA and the Act.

*Comment:* One commenter suggested that “it is a violation of statute to assign attorney adjudicators to render decisions that are less than fully favorable to a beneficiary because it deprives the beneficiary of an impartial ALJ, appointed and protected under the provisions of the APA.”

*Response:* We disagree with the commenter. In accordance with section 1869(b)(1)(A) of the Act, any individuals dissatisfied with an initial determination and reconsideration are entitled to a hearing, subject to timely filing and amount in controversy limitations, and (d)(1)(A) states that an ALJ “shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision *on such hearing*” (emphasis added). However, the rule we are finalizing, provides for a decision by another adjudicator (an attorney adjudicator) if such a hearing is waived under § 405.1038(b) or not required under § 405.1038(c), as finalized in this rule. As discussed above, no provision of the Act requires the Secretary to utilize an ALJ to issue a decision that does not require a hearing. OMHA will afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs, to help ensure an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

*Comment:* One commenter referred to the language in section II.B of the proposed rule where we stated that we believed well-trained attorneys could review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to

issue a decision in the appealed matter. 81 FR 43790, 43794. The commenter indicated “well-trained attorney” is not defined in the proposed regulation and asked whether a “well trained” attorney is required to be a member in good standing of a bar in the United States.

*Response:* Section § 405.902, as finalized in this rule, states an “Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.” A licensed attorney would be a member in good standing of a bar in the United States.

*Comment:* One commenter argued that proposed § 405.1006(e)(1)(ii), (e)(1)(iii) and (e)(2)(iii) may overcomplicate the process of aggregating claims because an attorney adjudicator could determine that the minimum amount in controversy was met, but would be required to refer the appeal to an ALJ if it appeared that the claims were not properly aggregated or if the appeal did not meet the required amount in controversy, in order for an ALJ to dismiss the request for hearing. The commenter also believed ALJs might simply adopt the attorney adjudicator’s preliminary determination, which could result in improperly denied requests for hearing.

*Response:* We appreciate the commenter’s perspective but believe these procedures are necessary to help ensure that a request for a hearing before an ALJ is reviewed by an ALJ before being dismissed for not meeting the amount in controversy required for an ALJ hearing. A referral to an ALJ would only be necessary when the attorney adjudicator believes the appealed claims do not meet the amount in controversy requirement and the aggregation request may not be valid, because the request for hearing would be subject to a possible dismissal for not meeting the amount in controversy requirement. Section 405.1006(e)(1) and (2), as finalized in this rule, provide that only an ALJ may determine that the claims were not properly aggregated and therefore do not meet the minimum amount in controversy required for an ALJ hearing. Thus, the ALJ is required to make this determination, and would not be permitted to simply adopt the attorney adjudicator’s preliminary determination without conducting an independent review. If an ALJ dismisses a request for hearing after determining that an aggregation request was not valid, and therefore the minimum amount in controversy was not met, and

the appellant does not agree with the dismissal, the appellant may request a review of the dismissal by the Council. Instructions for requesting a review by the Council will be included in the notice of dismissal sent to the appellant with the ALJ’s dismissal order.

After review and consideration of the comments received, and for the reasons discussed above and in the proposed rule, we are finalizing our proposals as discussed above without modification to provide authority for attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, dismissals when an appellant withdraws his or her request for an ALJ hearing, remands as provided in §§ 405.1056 and 423.2056 or at the direction of the Council, and reviews of QIC and IRE dismissals. Also, we are finalizing the definition of attorney adjudicator in § 405.902 as proposed without modification.

In addition, we are making a conforming technical revision to § 423.558(b) to replace “ALJ hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions” for consistency with the revised title of part 423, subpart U, and the revisions discussed above providing for attorney adjudicator reviews.

### 3. Application of 405 Rules to Other Parts

Current § 422.562(d) states that unless subpart M regarding grievances, organization determinations and appeals under the MA program provides otherwise, the regulations found in part 405 apply under subpart M to the extent appropriate. In addition, current § 422.608, which is a section within subpart M, provides that the regulations under part 405 regarding Council review apply to the subpart to the extent that they are appropriate. Pursuant to § 417.600, these rules governing MA organization determinations are also applicable to beneficiary appeals and grievances when the beneficiary is enrolled in a competitive medical plan or HMO (also known as “cost plan”) under section 1876 of the Act; therefore our discussion of MA proceedings applies also to cost plan appeals and grievances initiated under § 417.600.

Similar to current § 422.562(d), § 478.40(c) indicates that the part 405 regulations apply to hearings and appeals under subpart B of part 478 regarding QIO reconsiderations and appeals, unless they are inconsistent with specific provisions in subpart B. Thus, the part 405 rules are used, to the extent appropriate, for administrative review and hearing procedures in the

absence of specific provisions related to administrative reviews and hearing procedures in part 422, subpart M; and part 478, subpart B, respectively. These general references to part 405 are often helpful in filling in gaps in procedural rules when there is no rule on point in the respective part. However, as we stated in the proposed rule, there has been confusion on the application of part 405 rules when a part 405 rule implements a specific statutory provision that is not in the authorizing statute for the referring subpart and HHS has not adopted a similar policy for the referring subpart in its discretion to administer the MA, QIO, and cost plan appeals programs (81 FR 43795). For example, certain procedures and provisions of section 1869 of the Act (governing certain determinations and appeals under Medicare Part A and Part B) that are implemented in part 405, subpart I are different than or not addressed in sections 1155 (providing for reconsiderations and appeals of QIO determinations), 1852(g) (providing for appeals of MA organization determinations), and 1876 (providing for appeals of organization determinations made by section 1876 health maintenance organizations (HMOs) and competitive medical plans (CMPs)). Section 1869 of the Act provides for, among other things, redeterminations of certain initial determinations, QIC reconsiderations following redeterminations or expedited determinations; ALJ hearings and decisions following a QIC reconsideration; DAB review following ALJ decisions; specific time frames in which to conduct the respective adjudications; and, at certain appeal levels, the option to escalate appeals to the next level of appeal if the adjudication time frames are not met. In addition, section 1869(b)(3) of the Act does not permit providers and suppliers to introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration.

In contrast, sections 1852(g)(5) of the Act and 1876(c)(5)(B) of the Act incorporate some, but not all, of the provisions of section 1869 of the Act, and add certain requirements, such as making the MAO, HMO, or CMP a party to an ALJ hearing. For example, sections 1852(g)(5) and 1876(c)(5)(B) of the Act specifically incorporate section 1869(b)(1)(E)(iii) of the Act to align the amount in controversy requirements for an ALJ hearing and judicial review among the three sections. However,

sections 1852(g) and 1876(c)(5)(B) do not incorporate adjudication time frames and escalation provisions, or the limitation on new evidence provision of section 1869(b)(3) of the Act.

Additionally, section 1155 of the Act provides for an individual's right to appeal certain QIO reconsidered determinations made under section 1154 of the Act directly to an ALJ for hearing. However, section 1155 of the Act does not reference section 1869 of the Act or otherwise establish an adjudication time frame, and provides for a different amount in controversy requirement for an ALJ hearing.

Despite these statutory distinctions, HHS has established similar procedures by regulation to the extent practicable, when not addressed by statute. For example, section 1860D-4(h) of the Act, which addresses appeals of coverage determinations under Medicare Part D, incorporates paragraphs (4) and (5) of section 1852(g) of the Act. As discussed above, section 1852(g) does not incorporate adjudication time frames from section 1869 of the Act or otherwise establish such time frames. However, through rulemaking for Part D coverage determination appeals, HHS has adopted a 90-day adjudication time frame for standard requests for an ALJ hearing and requests for Council review of an ALJ decision, as well as a 10-day adjudication time frame when the criteria for an expedited hearing or review are met.

To clarify the application of the part 405 rules, we proposed revisions to parts 422 and 478. Specifically, we proposed in §§ 422.562(d) and 422.608 that the part 405 rules would not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1852 of the Act (81 FR 43796, 43876-43877). Similarly, we proposed in § 478.40(c) that the part 405 rules would not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1155 of the Act (81 FR 43890-43891). In addition, we proposed in § 478.40(c) to remove language that equates an initial determination and reconsidered determination made by a QIO to contractor initial determinations and reconsidered determinations under part 405 because that language has caused confusion with provisions that are specific to part 405 and QIC reconsiderations, and it is not necessary to apply the remaining part 405, subpart I procedural rules in part 478, subpart B proceedings. We stated in the proposed rule that, in addition to clarifying the application of part 405 rules to other parts, these revisions would help ensure that statutory

provisions that are specific to certain Medicare appeals are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals (81 FR 43796). In our discussion of these proposals, we identified the statutory differences in sections 1155 and 1852(g) of the Act compared to section 1869 discussed above.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received three comments on proposed §§ 422.562(d), 422.608, and 478.40(c), expressing concern that the added language is too general and does not address the specific changes that are intended by the proposals. The commenters indicated that the general language will create more confusion rather than clarifying existing ambiguity about which part 405 rules apply to MA program appeals under part 422, subpart M and to appeals of QIO reconsidered determinations under part 478, subpart B, and may have the unintended consequence of stripping away protections for unrepresented beneficiaries. Two of the commenters stated that the proposals will take away important safeguards that currently provide consistency in application of beneficiary rights across the appeals spectrum and provide answers in the absence of specific applicable provisions. The same commenters argued that under proposed §§ 422.562(d) and 422.608, part 405 rules apply to administrative reviews, hearing processes, and representation of parties "to the extent that they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act" but the only provisions of section 1869 of the Act that are referenced in section 1852(g)(5) of the Act relate to amounts in controversy. The commenters argued that the language of the proposals would mean that all sections of part 405, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. The same commenters used the part 405 rule in § 405.1018, which requires a good cause determination for the submission of new evidence by providers, suppliers, and beneficiaries represented by a provider or supplier, if such evidence was not submitted prior to the issuance of the QIC's reconsideration determination, as an example of where the proposals may have an unintended consequence of taking away a beneficiary safeguard. The

commenters suggested that if current § 405.1018(d), which states that the requirements of § 405.1018 do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, was not available in part 422, subpart M proceedings, then an enrollee in the MA program may not be able to invoke the protections in § 405.1018(d). All commenters requested that after the agency provides further details on which part 405 rules do not apply, it should provide the public with an opportunity to review the specific changes and allow them to make more meaningful comments on the proposal.

*Response:* We do not agree with the comment that the proposal would mean that all sections of part 405, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. The proposal related to part 405, subpart I provisions that implement requirements in section 1869 of the Act that are not also contained in section 1852(g). Section 1852(g)(5) of the Act, which is implemented in part 422, subpart M, does, as the commenter highlights, reference portions of section 1869 of the Act related to the amount in controversy threshold. However, section 1852(g)(5) of the Act also entitles an MA enrollee to "a hearing before the Secretary to the same extent as is provided in section 205(b) [of the Act]," which is also referenced in section 1869 of the Act. Thus, section 1852(g) of the Act includes certain provisions, in addition to the amount in controversy provisions, that are also in section 1869 of the Act. The provisions of part 405, subpart I that implement these provisions would continue to apply to part 422, subpart M appeals to the extent they are appropriate, and therefore the proposal would not mean that all sections of part 405, subpart I, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. Rather, as we explained in the preamble to the proposed rule, the proposal would serve to clarify that the provisions of part 405, subpart I that implement provisions of section 1869 of the Act that are not also addressed in sections 1852 and 1155 of the Act, are not appropriate to apply in appeals initiated under part 422, subpart M, and part 478, subpart B. Using the commenter's example of § 405.1018, only paragraphs (c) and (d)(2) specifically relate to a provision of section 1869 of the Act; specifically, as we explained in the proposed rule, section 1869(b)(3) of the Act does not permit providers and suppliers to

introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration. The other subsections of § 405.1018 do not effectuate a specific provision of section 1869 of the Act, but rather relate to the hearing before the Secretary, which is also required under section 1852(g) of the Act, and therefore applying the other subsections of § 405.1018 to part 422, subpart M would continue to be appropriate under the proposal.

Proposed §§ 422.562(d), 422.608, and 478.40(c) were intended to clarify the application of part 405 rules to appeals and hearings initiated under other parts and to help ensure that statutory provisions that are specific to appeals under section 1869 of the Act are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals. In explaining the proposal, we also provided examples of specific provisions in section 1869 of the Act that are not also in sections 1852 and 1155 of the Act, and therefore the proposal would impact the part 405, subpart I provisions that implement those specific provisions of section 1869 of the Act that we discussed in explaining the proposal. While we believe our proposals provided sufficient information and notice regarding the part 405, subpart I provisions that would not apply in MA program appeals under part 422, subpart M and in appeals of QIO reconsidered determinations under part 478, subpart B, commenters raised concerns that the proposal and proposed regulation text were not sufficiently detailed. In response to the commenters' concerns we are finalizing §§ 422.562(d), 422.608, and 478.40(c) with modifications to specify in greater detail those part 405 provisions that implement provisions of section 1869 of the Act that are not also applicable to sections 1852 or 1155 of the Act, and that we do not believe apply to part 422, subpart M and part 478, subpart B adjudications. We specifically discussed three such provisions in section II.C of the proposed rule. The three specific topics covered by part 405, subpart I that implement provisions of section 1869 of the Act and that we believe do not apply to part 422, subpart M and part 478, subpart B adjudications are: (1) Specific time frames to conduct adjudications at each level of administrative appeal (sections 1869(a)(3)(C)(ii), (c)(3)(C)(i),

(d)(1), and (d)(2) of the Act); (2) the option to request escalation of appeals when a QIC, OMHA, or the Council does not render a decision within an applicable adjudication time frame (sections 1869(c)(3)(C)(ii) and (d)(3) of the Act); and (3) the requirement that a provider or supplier, or beneficiary represented by a provider or supplier, must establish good cause to introduce evidence that was not presented at the reconsideration by the QIC (section 1869(b)(3) of the Act). Because these provisions of section 1869 of the Act were discussed in the proposed rule as examples of provisions that are not also included in sections 1852 and 1155 of the Act, and that we do not believe apply to appeals and hearings under part 422, subpart M and part 478, subpart B, and because these three areas have historically been the subject of the greatest confusion for appellants and OMHA staff regarding application of part 405 rules to other parts, we are finalizing the proposal with respect to those three areas. We will conduct additional notice and comment rulemaking if we identify additional provisions in the part 405, subpart I rules that implement provisions of section 1869 of the Act that are not also included in sections 1852(g) and 1155 of the Act, and we believe those provisions should not apply to part 422, subpart M and part 478, subpart B adjudications. Furthermore, we believe that listing the specific sections of part 405, subpart I that do not apply in MA program appeals under part 422, subpart M, and in appeals of QIO reconsidered determinations under part 478, subpart B addresses commenters' concerns regarding confusion or ambiguity.

Section 1869(d)(1)(A) of the Act provides that unless the appellant waives the statutory adjudication time frame, the ALJ conducts and concludes a hearing on a decision of the QIC and renders a decision no later than the end of the 90-day period beginning on the date a request for hearing is timely filed. In addition, section 1869(d)(2) of the Act provides that the DAB conducts and concludes a review of the decision on a hearing and renders a decision no later than the end of the 90-day period beginning on the date a request for review is timely filed. Sections 1852(g)(5) and 1155 of the Act do not contain similar adjudication time frames for an ALJ and DAB to render a decision. Therefore, we are specifying in §§ 422.562(d) and 478.40(c), and in § 422.608 through reference to § 422.562(d)(2), that the adjudication time frames at the OMHA level and the Council in part 405 do not apply in

proceedings under either part 422, subpart M or part 478, subpart B. Similarly, because the part 405 escalation provisions originate in section 1869(c)(3)(C)(ii) and (d)(3) of the Act and are not incorporated into sections 1852(g) or 1155 of the Act, and the part 405 rules for adjudication time frames for an ALJ or the Council do not apply, we are specifying that the options to request escalation of an appeal in part 405 do not apply in proceedings under either part 422, subpart M or part 478, subpart B. In addition, we do not think it would be appropriate to apply the part 405, subpart I rules to time frames for adjudications below the OMHA level for Part C and QIO appeals because those parts already contain regulations regarding time frames and expediting appeals that are different from the part 405, subpart I provisions. For example, under § 422.572(f) and § 422.590(g), if an MAO fails to provide the enrollee with timely notice of an expedited organization determination or expedited reconsideration, the failure constitutes an adverse determination; the adverse decision then, respectively, is subject to appeal or must be forwarded to the IRE. With respect to OMHA-level adjudication time frames and the option to escalate an appeal from the OMHA level to the Council, we note that § 405.1016, as finalized in this rule, applies only to requests for a hearing filed after a QIC has issued a reconsideration. In the final rule establishing the MA program, CMS stated that part 405 regulatory provisions that are dependent upon QICs would not apply to part 422, subpart M adjudications because an IRE—not a QIC—conducts reconsiderations for MA appeals (70 FR 4588, 4676). We believe the same rationale extends to reconsiderations conducted by a QIO under part 478, subpart B. We also believe it is unwise to extend the adjudication time frames to additional cases or to create an option for escalation of an appeal where such provisions are not required by statute given the current volume of pending appeals at OMHA and the Council. However, we note that the vast majority of MA and QIO appeals are filed by beneficiaries and enrollees, and current OMHA and Council policy provides for the prioritization of appeals filed by beneficiaries or enrollees. Thus, we anticipate that there will be little change in adjudicatory processing times for most appellants in MA program appeals and appeals of QIO reconsidered determinations. Accordingly, we do not believe that the policies we are finalizing above will take away current

protections or safeguards for beneficiaries.

In addition, section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC reconsideration unless there is good cause that precluded the introduction of such evidence at or before that reconsideration. Several provisions in part 405 implement this limitation on the submission of new evidence by providers and suppliers, as well as beneficiaries represented by providers and suppliers, and further implement rules for the review of whether good cause exists for late submissions. Neither section 1852(g)(5) nor section 1155 of the Act contains a similar limitation on the submission of new evidence by providers and suppliers if such evidence was not presented at an earlier stage in the appeal proceedings. Furthermore, the requirement to show good cause for the introduction of new evidence applies to evidence that was not presented at the QIC reconsideration and, as noted above, part 405 provisions that are dependent upon QICs do not apply to adjudications under part 422, subpart M, and we believe the same rationale extends to reconsiderations conducted by QIOs under part 478, subpart B. Therefore, we are specifying in §§ 422.562(d) and 478.40(c), and in § 422.608 through reference to § 422.562(d)(2), that the good cause limitations on new evidence submitted by providers, suppliers, and beneficiaries represented by a provider or supplier, outlined in part 405, subpart I do not apply in proceedings under part 422, subpart M or part 478, subpart B. Although two commenters expressed concern that the proposals could mean that an enrollee in the MA program would not be able to invoke the protection of current § 405.1018(d), these finalized rules specifically identify §§ 405.1018(c), 405.1028(a), and 405.1122(c) as part 405 sections that do not apply in part 422, subpart M, and therefore the protections afforded to unrepresented beneficiaries in current § 405.1018(d) are unnecessary in part 422, subpart M appeals because there is no need for any appellant in a Part C appeal to show good cause for the introduction of new evidence for the first time at the OMHA level. As we stated above, we do not believe that the policies we are finalizing will take away current protections or safeguards for beneficiaries appealing an MA organization determination (or cost plan determination) or appealing from a QIO determination.

After review and consideration of the comments received, for the reasons

discussed above and in the proposed rule, we are finalizing the following changes to §§ 422.562(d), 422.608, and 478.40(c). We are specifying in §§ 422.562(d) and 478.40(c), and in 422.608 through reference to § 422.562(d)(2), those specific provisions of part 405, subpart I discussed in the proposed rule that are not applicable to MA program appeals under part 422, subpart M or appeals of QIO reconsidered determinations under part 478, subpart B, as discussed above. The provisions we are specifying are: (1) § 405.950 (time frames for making a redetermination); (2) § 405.970 (time frame for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level); (3) § 405.1016 (time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council); (4) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b) and the time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d); (5) § 405.1132 (request for escalation to Federal court); and (6) §§ 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c) and any other references to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

#### 4. OMHA References

When the 2005 Interim Final Rule was published in March 2005, implementing the part 405, subpart I rules, OMHA was not yet in operation. Further, processes and procedures were being established under the part 405 subpart I rules, with new CMS contractors and the newly transitioned ALJ hearing function. Since that time, OMHA and CMS and its contractors have developed operating arrangements to help ensure appeals flow between CMS contractors and OMHA, and that appeal instructions for appellants provide clear direction on how and where to file requests for hearings and reviews. However, many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule, and OMHA is not mentioned in the regulation text.

To provide clarity to the public on the role of OMHA in administering the ALJ

hearing program, and to clearly identify where requests and other filings should be directed, we proposed to define OMHA in § 405.902 as the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act. We also proposed to amend rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. To implement these changes, we proposed to revise provisions throughout part 405 subparts I and J, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections in section III of the proposed rule.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received three comments on this proposal. One commenter supported the proposal as necessary to update regulatory language to clearly reflect the role of OMHA in administering ALJ appeals. Two commenters opposed the proposal. One commenter argued that each change from "ALJ" to "OMHA" takes a specific power granted directly to an ALJ adjudicating a case and transfers it to OMHA administrators. Another commenter interpreted the proposal as a transfer of control over ALJs' workloads from ALJs to OMHA.

*Response:* We disagree with the commenters' interpretation of the proposal as a transfer of authority from ALJs to OMHA administrators. Rather, the proposal provides clarity to the public on the role of OMHA in administering the ALJ hearing program and clearly identifies where requests and other filings should be directed to ease appellant confusion and more efficiently process appeals by helping to ensure filings are properly routed. As discussed above (and in section II.D of the proposed rule), many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule. OMHA was not yet in operation or mentioned in the regulation text at the time the Interim Final Rule was published in March 2005. We believe that reference to OMHA or an OMHA office in place of current references to an unspecified entity, ALJs, and ALJ hearing offices

would provide a clearer explanation of a topic in certain regulations and would clarify areas of the regulations that may have confused appellants in the past. For example, current § 405.970(e)(2)(ii) states that, for cases that have been escalated from the reconsideration level of appeal to the OMHA level of appeal, the QIC forwards the case file “to the ALJ hearing office.” The concept of an ALJ hearing office is most analogous to OMHA’s individual field offices. In practice, however, the QIC sends case files for escalated cases to a centralized location, not to individual field offices. Thus, we believe reference to OMHA would be more appropriate here. Similarly, as another example, current § 405.1104 states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be “pending before the ALJ” at the end of an applicable adjudication time period under § 405.1016 may request to escalate the appeal to the Council level of review. However, appeals that are eligible to be escalated may be unassigned and not yet before an ALJ. Thus, we believe that it would be appropriate to state “pending with OMHA” in this regulation (see § 405.1016(f)(1), as finalized).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals without modification to define OMHA and replace certain references to ALJs, ALJ hearing offices, and unspecified entities with a reference to OMHA or an OMHA office.

#### 5. Medicare Appeals Council References

The Council is currently referred to as the “MAC” throughout current part 405, subpart I; part 422, subpart M; and part 423, subparts M and U. This reference has caused confusion in recent years with the transition from Fiscal Intermediaries and Carriers, to Medicare administrative contractors—for which the acronym “MAC” is also commonly used—to process claims and make initial determinations and redeterminations in the Medicare Part A and Part B programs. In addition, current §§ 422.618 and 422.619 reference the Medicare Appeals Council but use “Board” as the shortened reference, and part 478, subpart B, references the DAB as the reviewing entity for appeals of ALJ decisions and dismissals but the Council is the entity that conducts reviews of ALJ decisions and dismissals, and issues final decisions of the Secretary for Medicare appeals under part 478, subpart B.

To address potential confusion with references to Medicare administrative

contractors and align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals throughout part 405, subpart I; part 422, subpart M; and part 423, subparts M and U, we proposed to amend the following rules to replace “MAC” or “Board” with “Council”: §§ 405.902, 405.904, 405.906, 405.908, 405.910, 405.926, 405.980, 405.982, 405.984, 405.990, 405.1026, 405.1036, 405.1037, 405.1042, 405.1046, 405.1048, 405.1050, 405.1052, 405.1054, 405.1060, 405.1062, 405.1063, 405.1100, 405.1102, 405.1104 (as re-designated and revised as proposed § 405.1016(e)–(f)), 405.1106, 405.1108, 405.1110, 405.1112, 405.1114, 405.1116, 405.1118, 405.1120, 405.1122, 405.1124, 405.1126, 405.1128, 405.1130, 405.1132, 405.1134, 405.1136, 405.1138, 405.1140, 422.561, 422.562, 422.608, 422.612, 422.616, 422.618, 422.619, 422.622, 422.626, 423.560, 423.562, 423.1968, 423.1974, 423.1976, 423.1978, 423.1980, 423.1982, 423.1984, 423.1990, 423.2026, 423.2036, 423.2042, 423.2046, 423.2048, 423.2050, 423.2052, 423.2054, 423.2062, 423.2063, 423.2100, 423.2102, 423.2106, 423.2108, 423.2110, 423.2112, 423.2114, 423.2116, 423.2118, 423.2120, 423.2122, 423.2124, 423.2126, 423.2128, 423.2130, 423.2134, 423.2136, 423.2138, and 423.2140.

In addition, to align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals in part 478, subpart B, we proposed to amend §§ 478.46 and 478.48 to replace “Departmental Appeals Board” and “DAB,” with “Medicare Appeals Council” and “Council”.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received two comments on this proposal—one of which was a collective comment submitted by the four then-current CMS DME Medicare Administrative Contractors (MACs). Both comments supported the proposal to replace references to “MAC” with “Council” as necessary to reduce confusion between the Council and CMS Medicare Administrative Contractors.

*Response:* We thank the commenters for their support and agree that the proposed revisions will reduce confusion.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals without modification to replace references to “MAC” and “Board,” with “Council” in the sections listed above, and to replace references to “Departmental Appeals Board” and “DAB” with “Medicare Appeals

Council” and “Council” in §§ 478.46 and 478.48. In addition to the sections listed above, we are also making a conforming technical revision to § 423.558(b) to replace the reference to “MAC” in § 423.558(b) with “Council.”

#### B. Specific Provisions of Part 405, Subpart I and Part 423, Subparts M and U

##### 1. Overview

Part 405, subpart I and part 423, subpart U contain detailed procedures for requesting and adjudicating a request for an ALJ hearing, and a request for a review of a QIC or IRE dismissal. Part 423, subpart U provisions were proposed in the March 17, 2008 **Federal Register** (73 FR 14342) and made final in the December 9, 2009 **Federal Register** (74 FR 65340), and generally follow the part 405, subpart I procedures. In this final rule, we generally discuss provisions of the proposed rule related to part 405, subpart I, and then whether any aligning revisions to part 423, subpart U, were proposed, unless a provision is specific to part 405 and there is no corresponding part 423 provision. We then discuss the policies we are finalizing in this final rule related to parts 405 and 423.

##### 2. General Provisions, Reconsiderations, Reopenings, and Expedited Access to Judicial Review

###### a. Part 423, Subpart M General Provisions (§ 423.562)

Current § 423.562(b)(4) lists the appeal rights of a Part D plan enrollee, if the enrollee is dissatisfied with any part of a coverage determination. Specifically, paragraph (b)(4)(v) describes the right to request Council review of the ALJ’s hearing decision if the ALJ affirms the IRE’s adverse coverage determination in whole or in part, and paragraph (b)(4)(vi) describes the right to judicial review of the hearing decision if the Council affirms the ALJ’s adverse coverage determination in whole or in part, and the amount in controversy requirements are met. We proposed revisions to paragraphs (b)(4)(v) and (vi) to account for the possibility that an appeal at the OMHA level could be decided by an attorney adjudicator or by an ALJ without conducting a hearing. 81 FR 43790, 43797. We proposed to revise paragraph (b)(4)(v) to insert “or attorney adjudicator” after each instance of “the ALJ.” We stated in the proposed rule that this proposal was necessary to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is

conducted as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), by stating the right to request Council review of an attorney adjudicator decision that affirms the IRE's adverse coverage determination. We also proposed to remove "hearing" before "decision" in paragraph (b)(4)(v) to reflect that an attorney adjudicator issues decisions without conducting a hearing, and an ALJ may issue a decision without conducting a hearing.

In paragraph (b)(4)(vi), we proposed to remove "ALJ's" and insert "ALJ's or attorney adjudicator's" in its place to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), by including an attorney adjudicator's decision as a decision that may be affirmed by the Council. We also proposed to remove "hearing" before "decision" in paragraph (b)(4)(vi) because while the Council may conduct a hearing, Council decisions are generally issued without conducting a hearing, and the decision of the Council is subject to judicial review.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 423.562 as proposed without modification.

**b. Part 423, Subpart U Title and Scope (§ 423.1968)**

The current heading of part 423, subpart U references ALJ hearings but does not reference decisions. We proposed to revise the heading by replacing "ALJ Hearings" with "ALJ hearings and ALJ and attorney adjudicator decisions" to reflect that subpart U covers decisions by ALJs and attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43797.

Current § 423.1968 explains the scope of the requirements in subpart U. We proposed in § 423.1968 to expand the scope of subpart U to include actions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR

43790, 43797. Specifically, we proposed at § 423.1968(a) to add that subpart U sets forth requirements relating to attorney adjudicators with respect to reopenings; at § 423.1968(b) to add that subpart U sets forth requirements relating to ALJ decisions and decisions of attorney adjudicators if no hearing is conducted; and at § 423.1968(d) to add that subpart U sets forth the requirements relating to Part D enrollees' rights with respect to ALJ hearings and ALJ or attorney adjudicator reviews. We stated that these changes are necessary to accurately describe the scope of the revised provisions of subpart U to implement the attorney adjudicator proposal discussed in section II.B of the proposed rule and II.A.2 of this final rule above.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 423.1968 as proposed without modification.

**c. Medicare Initial Determinations, Redeterminations and Appeals: General Description (§ 405.904)**

Section 405.904(a) provides a general overview of the entitlement and claim appeals process to which part 405, subpart I applies. Current paragraphs (a)(1) and (a)(2) provide that if a beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, the beneficiary may request that the Council review the case. To provide for the possibility that a decision may be issued without conducting a hearing by an ALJ, as permitted under current rules, or an attorney adjudicator, as proposed in II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), we proposed to add language in paragraphs (a)(1) and (a)(2) to provide that if the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator when no hearing is conducted, the beneficiary may request that the Council review the case. We stated in the proposed rule that this would provide a comprehensive overview of the entitlement and claim appeals process, with information on the potential for and right to appeal decisions by ALJs when no hearing is

conducted, and the right to appeal decisions by attorney adjudicators. 81 FR 43790, 43797.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on this proposal. The commenter supported our proposal as necessary to ensure that beneficiaries' concerns were given appropriate consideration by clearly stating that there is a right to request that the Council review a case when no hearing is conducted and a decision is issued by an ALJ or attorney adjudicator.

*Response:* We thank the commenter for its support. We believe the changes will help beneficiaries (and others appellants pursuant to § 405.904(b)) understand that they have the same right to appeal decisions by ALJs when no hearing is conducted, or decisions by attorney adjudicators, as they currently have to appeal decisions by an ALJ when a hearing is conducted.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.904 as proposed, with the following modifications. We are removing "Administrative Law Judge (ALJ)" and "Medicare Appeals Council (Council)" from paragraph (a)(1) and adding "ALJ" and "Council" in their places, respectively, for consistency with the rest of part 405, subpart I and because the term "ALJ" is already defined in § 405.902.

**d. Parties to the Initial Determinations, Redeterminations, Reconsiderations Proceedings on a Request for Hearing, and Council Review (§ 405.906)**

Section 405.906 discusses parties to the appeals process and subsection (b) addresses parties to the redetermination, reconsideration, hearing and MAC. We proposed in the paragraph heading and introductory text to subsection (b) to replace the phrases "hearing and MAC" and "hearing, and MAC review," respectively, with "proceedings on a request for hearing, and Council review" because, absent an assignment of appeal rights, the parties are parties to all of the proceedings on a request for hearing, including the hearing if one is conducted, and they are parties to the Council's review. 81 FR 43790, 43797.

We received no comments on this proposal, other than comments in support of our general proposals to replace references to "MAC" and "Board," with "Council," and to replace references to "Departmental Appeals Board" and "DAB" with "Medicare Appeals Council" and "Council," as



discussed in section II.A.5 above. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.906 as proposed without modification.

e. Medicaid State Agencies (§ 405.908)

Section 405.908 discusses the role of Medicaid State agencies in the appeals process and states that if a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC and judicial review levels. We proposed to replace “ALJ” with “OMHA” to provide that the State agency has party status regardless of the adjudicator assigned to the State agency’s request for an ALJ hearing or request for review of a QIC dismissal at the OMHA level of review, as attorney adjudicators may issue decisions on requests for hearing and adjudicate requests for reviews of QIC dismissals, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43797–43798.

Provided below is a summary of the specific comment received and response to the comment:

*Comment:* We received one comment on this proposal. The commenter supported the proposal to clarify that Medicaid State agencies that file a request for redetermination have the right to retain party status at the OMHA level regardless of whether a case is assigned to an ALJ or to an attorney adjudicator. However, the commenter asked that the term “OMHA level of review” be replaced with “and attorney adjudicator or ALJ review,” or, alternatively, that the term “OMHA level of review” be defined as the level of review that entails review by an ALJ or attorney adjudicator, and used consistently throughout the regulations. The commenter expressed concern that the term “OMHA level of review” could be confusing because the term is not currently in common use.

*Response:* We thank the commenter for the recommendation. As a preliminary matter, we note that the changes proposed in § 405.908 to which the commenter is referring would revise the last sentence to read, “If a State agency files a request for redetermination, it may retain party status at the QIC, OMHA, Council, and judicial review levels.” The word “review” in this sentence is part of the term “judicial review” as described in § 405.1136, rather than a general descriptor of all levels of appeal. Therefore, we believe the term to which the commenter objects can more accurately be described as the “OMHA level.” We believe the term “OMHA

level” provides a convenient shorthand for referring to the adjudication level that entails an ALJ hearing, or an on-the-record review by an ALJ or attorney adjudicator, and we note that the term is also used in proposed §§ 405.910, 405.956, 405.976, 405.1028, 405.1032, 405.1046, 405.1100, 405.1108, 405.1110, 405.1122, 423.2032, 423.2110, and 423.2122. We do not share the commenter’s concern that the term as used in proposed § 405.908 or elsewhere in part 405, subpart I or part 423, subparts M and U is confusing, especially in light of the proposed addition of “OMHA” and “attorney adjudicator” to the definitions being finalized in § 405.902, which collectively define OMHA as administering the ALJ hearing process in accordance with section 1869(b)(1) of the Act, and attorney adjudicators as employees of OMHA who are authorized to take actions under subpart I on requests for ALJ hearing.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.908 as proposed without modification.

f. Appointed Representatives (§ 405.910)

As described below, we proposed a number of revisions to the rules in § 405.910 concerning the appointment of a representative to act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. 81 FR 43790, 43798–43799. The 2002 Proposed Rule (67 FR 69318 through 69319) explained that the § 405.910 requirements for a valid appointment of a representative are necessary to help ensure that adjudicators are sharing and disseminating confidential information with the appropriate individuals. The 2005 Interim Final Rule (70 FR 11428 through 11431) adopted a general requirement to include a beneficiary’s health insurance claim number (HICN) for a valid appointment of a representative in § 405.910(c)(5). The SMART Act Final Rule (80 FR 10614, 10617) revised § 405.910(c)(5) to explicitly limit the requirement to include a beneficiary’s HICN to instances in which the beneficiary is the party appointing a representative. However, the Medicare manual provision for completing a valid appointment of representative (Medicare Claims Processing Manual (Internet-Only Manual 100–4), chapter 29, section 270.1.2) details the requirements for an appointment of representation to contain a unique identifier of the party being represented.

Specifically, if the party being represented is the beneficiary, the Medicare number must be provided, and if the party being represented is a provider or supplier, the National Provider Identifier (NPI) number should be provided. Additionally, the official form for executing a valid appointment of representative (form CMS–1696 (OMB No. 0938–0950), available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1696.pdf>) provides a blank space for the party to include a Medicare or NPI number. To assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, we proposed to revise § 405.910(c)(5) to add a requirement to include the Medicare NPI of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative. We stated in the proposed rule that we were retaining the requirement to identify the beneficiary’s Medicare HICN when the beneficiary is the party appointing a representative.

Section 405.910 also addresses defective appointments, and delegations and revocations of appointments. However, there has been confusion on the effects on the adjudication of an appeal when a defective appointment must be addressed, or when an adjudicator is not timely informed of a delegation or revocation of an appointment. To address the effect of a defective appointment on the adjudication of an appeal to which an adjudication time frame applies, we proposed to add § 405.910(d)(3), which would extend an applicable adjudication time frame from the later of (1) the date that a defective appointment of representative was filed or (2) the date the current appeal request was filed by the prospective appointed representative, to the date that the defect in the appointment was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative. We proposed this revision because, in accordance with § 405.910(d)(1) and (d)(2), a prospective appointed representative lacks the authority to act on behalf of a party and is not entitled to obtain or receive any information related to the appeal. Thus, contact with the party may be necessary to obtain missing information from the appointment, which may delay adjudicating the appeal until the appointment is cured or the party decides to proceed with the appeal without a representative. However, we proposed that if the request was filed by a prospective

appointed representative, the request would be considered filed for the purpose of determining timeliness of the request, even if the individual is not the appointed representative after the appointment is cured, or the party decides to proceed with the appeal without a representative.

We also proposed at § 405.910(f)(1) to replace “ALJ level” with “OMHA level” so there would be no confusion that proceedings at the OMHA level are considered proceedings before the Secretary for purposes of appointed representative fees, regardless of whether the case is assigned to an ALJ or attorney adjudicator.

Section 405.910(i)(2) and (i)(3) provide that if an appeal involves an appointed representative, an ALJ sends notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative. We proposed to insert “or attorney adjudicator” after “ALJ” in § 405.910(i)(2) and (i)(3). This would provide that attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), like an ALJ under the current provisions, would send notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative.

A representative and/or the represented party is responsible for keeping the adjudicator of a pending appeal current on the status of the representative. In practice, sometimes adjudicators are not informed of a delegation or revocation of an appointment of representative that has been filed for an appeal, which results in confusion and potentially duplicative or unnecessary proceedings. We proposed to revise § 405.910(l)(2) (which, as described later, we proposed to re-designate as (l)(1)(ii)) to add that a delegation is not effective until the adjudicator receives a copy of the party’s written acceptance of the delegation, unless the representative and designee are attorneys in the same law firm or organization, in which case the written notice to the party of the delegation may be submitted if the acceptance is not obtained from the party. This revision would emphasize the importance of keeping adjudicators current on the status of the representative and also state the effects of failing to do so. The revisions we proposed to § 405.910(l)(2) (re-designated as proposed (l)(1)(ii)) would also serve to assist adjudicators in sharing and disseminating confidential information only with appropriate

individuals, and to provide adjudicators with appropriate contact information for scheduling purposes. To accommodate proposed paragraph (l)(2), we proposed to re-designate current paragraph (l), except for the title of the paragraph, as paragraph (l)(1), and to also re-designate the current subparagraphs accordingly. In addition, we proposed to add a missing “by” in current paragraph (l)(1)(ii) (re-designated as (l)(1)(i)) of § 405.910 to indicate that a designee accepts to be obligated “by” and comply with the requirements of representation. We also proposed to revise language in current paragraph (l)(2) (re-designated as proposed (1)(l)(ii)) of § 405.910 to clarify that “this signed statement” refers to the “written statement signed by the party,” and the written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice of intent to delegate under paragraph (l)(1)(i) indicates that fact. To further emphasize the importance of keeping adjudicators current on the status of the representative and clarify the effects of failing to do so, we also proposed to add at § 405.910(l)(3) and (m)(4) that a party’s or representative’s failure to notify the adjudicator that an appointment of representative has been delegated or revoked, respectively, is not good cause for missing a deadline or not appearing at a hearing.

We did not propose any changes for part 423, subpart U because it does not have a corresponding provision for representative appointments.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Two commenters expressed concern that the proposed changes will not resolve the inefficiencies and inconsistencies that parties currently experience when appointing and changing representatives. The commenters recommended that instead of adding additional regulations, changes are needed in OMHA’s internal procedures for receiving and processing appointments of representatives and changes in representatives to ensure that these appointments and changes are processed efficiently and consistently.

*Response:* OMHA is currently implementing several tools that we believe will assist with making our internal processing procedures more consistent, more efficient, and more appellant-friendly. The OCPM, available on the OMHA Web site, establishes uniform day-to-day procedures for processing appeals at the OMHA level of adjudication, including a detailed

chapter outlining procedures related to representatives. OMHA is also developing an electronic case management system that will streamline case processing and will have a public facing portal for appellants and representatives to electronically file documents, including relevant appointment of representative forms, and to check the status of appeals online. OMHA maintains a toll free beneficiary help line and an OMHA national toll free line to assist beneficiaries and other appellants with questions regarding their appeals. Finally, OMHA provides in-house training periodically to its ALJs, attorneys, and other staff to help ensure understanding and compliance with all regulations and internal policy applicable to processing appeals. We anticipate that these tools and ongoing training will help improve OMHA’s case processing and address the commenters’ concerns. However, we note that OMHA is responsible for protecting the personally identifiable information and protected health information contained in the administrative record, and as such, requires changes in representation to be filed for each appeal to which the change is applicable. We believe the tools discussed above and the proposed changes to the regulation that we are adopting in this final rule, will help to ensure the administrative record for the appeal is complete, and the authorization for the representative to receive appeal-related information is present for each appeal.

*Comment:* One commenter asked whether the regulations required use of the beneficiary’s entire Medicare health insurance claim number (HICN) for a valid appointment of representative or if an abbreviated HICN is adequate, and whether it is statutorily required to send a copy of the appointment of representative form to the other parties when the representative files an appeal or if it is sufficient to include it only in the copy of the appeal request that is sent to the “DME MAC, QIC, ALJ, or adjudicator.”

*Response:* We note as an initial matter that the proposed changes to § 405.910 do not specifically address or impact either of the questions asked by the commenter. The regulation at § 405.910(c)(5), which is also carried over into § 405.910(c)(5) as finalized in this rule, requires that when a beneficiary is the represented party, a valid appointment must include the beneficiary’s HICN. The language of the regulation does not permit an abbreviated or partial identification and therefore a complete HICN is required. With respect to the commenter’s second

question, the regulation at § 405.910(c)(7), which is carried over into the § 405.910(c)(7) as finalized in this rule, states that to be valid, the appointment of representation must be filed with the entity processing the party's initial determination or appeal. There is no requirement in section 1869 of the Act or in part 405, subpart I to send a copy of an appointment of representative to other parties to the appeal. While section III.A.3.g.v of the proposed rule (discussed in section II.B.3.g.v of the final below) addresses certain copy requirements when submitting a request for hearing, the Appointment of Representative form is not specifically addressed in that section. Section 405.1014(d)(1), as finalized in this rule, states that if additional materials submitted with a request are necessary to provide the information required for a complete request in accordance with § 405.1014(b), copies of those materials must be sent to the other parties as well. With respect to representative information, § 405.1014(a)(1)(iii), as finalized in this rule, specifies that a request for hearing must contain the name, address, and telephone number of the designated representative and does not separately require that the appellant also provide a copy of the Appointment of Representative form. However, to the extent the request for hearing does not otherwise contain this information, a copy of the Appointment of Representative form may be sent to the other parties to fulfill this requirement. With regard to appeals filed with a Medicare Administrative Contractor and QIC, there is no requirement, statutory or otherwise, that an appellant provide a copy of a request for appeal or any other filings to the other parties to the appeal. Although the commenter did not specifically mention requests for review filed with the Council, we note that § 405.1106(a) and (b), as finalized in this rule, require that appellants send requests for Council review or request for escalation to the entity specified in the notice of the ALJ's or attorney adjudicator's action or to OMHA respectively, and copies of the request to the other parties who received notice of the ALJ or attorney decision or dismissal or the QIC reconsideration, respectively. Section 405.1112, as finalized, requires that the request for review or escalation contain the name and signature of the representative. As with requests for an ALJ hearing, if the request for Council review or escalation does not otherwise include the representative's name or signature, a copy of the Appointment of

Representative form may be sent to the other parties in fulfillment of the copy requirements in § 405.1106(a) and (b).

*Comment:* Two commenters noted that the official form used for appointment of a representative (CMS-1696) required revisions to address certain appointments and representatives. One commenter indicated that the form did not provide for a physician's National Provider Identification number (NPI) when the party being represented is a physician. Another commenter noted that the form should include a place for a health plan to indicate "the name/title of [its] representative and whether they will be attending as a witness, representative, or medical expert."

*Response:* Form CMS-1696 provides that when the party being represented is a provider, the provider's NPI must be provided, and contains a box at the top of the form after the party name for either the HICN or National Provider Identifier number. In the context of an NPI, the term "provider" has been given a broader definition than in other Medicare contexts. When the final rule adopting the NPI as the standard unique health identifier for health care providers for use in the health care system was published in 2004, the term "health care provider" was defined as "a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business." 45 CFR 160.103. In § 405.902, the term "provider" is defined more narrowly as "a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services." "The term "supplier" is separately defined as "unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare."

Consistent with existing Medicare manual provisions found in chapter 29, section 270.1.2 of the Medicare Claims Processing Manual (Internet-Only Manual 100-4), § 405.910(c)(5), as

finalized in this rule, expressly requires that when a provider or supplier is the party appointing a representative, the provider's or supplier's NPI must be provided in order to create a valid appointment, and a physician is included in the § 405.902 definition of supplier. We thank the commenters for the suggestion to revise form CMS-1696, and may consider the suggestion for potential future clarification to the form. However, we note that the regulation is the binding authority, and parties wishing to appoint a representative must comply with the requirements of § 405.910.

With respect to the second comment, the commenter is correct that form CMS-1696 does not currently address appointment of a representative by a health plan. The MAO is a party to a Part C MA appeal, and an applicable plan (which may be a health plan) may be a party to an appeal involving a Medicare Secondary Payer (MSP) overpayment recovery assessed against the applicable plan. Although the form does not currently address health plans, health plans may use form CMS-1696, instead of a providing a separate notice that complies with § 405.910(c). However, in our experience, the individuals who file an appeal or appear at a hearing on behalf of health plans are generally employees of the plan, including medical directors, physician or nurse advisors, regulatory analysts, or in-house counsels. Indeed, this appears consistent with the commenter's request for a space to indicate whether the "representative" will be attending as a witness, representative, or medical expert. An appointment of representation under § 405.910 is not necessary where an individual who is employed by the plan is the person filing the appeal or appearing on behalf of the plan, and a representative, as that term is used in § 405.910, generally does not serve as a witness or medical expert in an appeal. Nevertheless, there may be instances where a health plan or applicable plan wishes to appoint a non-employee representative. In these instances § 405.910(a) is clear that any party to an appeal may appoint a representative. We note, however, that health plans and applicable plans that opt to use form CMS-1696 to appoint a representative would not have HICNs or NPIs, and would not need to complete that box, and we did not propose to require that another unique identifier be included in appointments of representative where a health plan or applicable plan is the party being represented.

After review and consideration of the comments received, for the reasons

discussed above and in the proposed rule, we are finalizing the changes noted above to § 405.910 as proposed without modification.

**g. Actions That Are Not Initial Determinations (§ 405.926)**

Current § 405.926(l) provides that an ALJ's decision to reopen or not to reopen a decision is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. In section III.A.2.l of the proposed rule, we proposed to revise the reopening rules to provide that attorney adjudicators would have the authority to reopen their decisions to the same extent that ALJs may reopen their decisions under the current provisions. We proposed to insert "or attorney adjudicator's" after "ALJ's" in § 405.926(l) to provide that the attorney adjudicator's decision to reopen or not to reopen a decision also is an action that is not an initial determination and therefore not an appealable action under subpart I. 81 FR 43790, 43799.

Current § 405.926(m) provides that a determination that CMS or its contractors may participate in or act as parties in an ALJ hearing is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. As explained in section III.A.3.f of the proposed rule and II.B.3.f of this final rule below, we proposed to revise § 405.1010, which currently discusses when CMS or a contractor may participate in an ALJ hearing. As explained in the proposal to revise § 405.1010, CMS or a contractor may elect to participate in the proceedings on a request for an ALJ hearing for which no hearing is conducted, in addition to participating in an ALJ hearing as a non-party participant. To align with our proposed revision to § 405.1010, we proposed to revise § 405.926(m) to indicate that CMS or its contractors may participate in the full scope of the proceedings on a request for an ALJ hearing, including the hearing, by replacing "participate in or act as parties in an ALJ hearing," with "participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing." 81 FR 43790, 43799.

We received no comments on these proposals, other than: (1) Comments discussed in section II.A.2 of the final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney

adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in sections III.A.3.f.i through III.A.3.f.iii of this final rule below related to our proposals regarding CMS and CMS contractors as participants or parties in the adjudication process. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.926 as proposed without modification.

**h. Notice of a Redetermination (§ 405.956)**

Current § 405.956(b)(8) requires that the notice of a redetermination include a statement that evidence not submitted to the QIC is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously. We proposed to remove "an ALJ hearing" and add "the OMHA level" in its place so that the notice of a redetermination is clear that, absent good cause and subject to the exception in § 405.956(d) for beneficiaries not represented by a provider or supplier, evidence that was not submitted to the QIC is not considered by an ALJ or an attorney adjudicator, as defined in section II.B of the proposed rule and II.A.2 of this final rule above. 81 FR 43790, 43799.

We received no comments on this proposal, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.956 as proposed without modification.

**i. Time Frame for Making a Reconsideration Following a Contractor Redetermination, Withdrawal or Dismissal of a Request for a Reconsideration, and Reconsideration (§§ 405.970, 405.972, and 405.974)**

As discussed in the 2005 Interim Final Rule (70 FR 11444 through 11445) and the 2009 Final Rule (74 FR 65311 through 65312), HHS adopted a policy of providing for one level of administrative review of a dismissal of a request for appeal. As a result, an adjudicator's decision or dismissal when reviewing a dismissal action

issued at the previous level is binding and not subject to further review. The policy balances a party's need for review and the need for administrative finality. The policy is embodied in the rules relating to reviews of dismissals at the next adjudicative level in §§ 405.972(e), 405.974(b)(3), 405.1004(c), 405.1102(c), 405.1108(b), and 405.1116.

At the QIC level of appeal, a review of a contractor redetermination and a review of a contractor's dismissal of a request for a redetermination are both characterized as a "reconsideration." While the outcome of a QIC's reconsideration of a contractor dismissal is differentiated and further reviews are not permitted in accordance with § 405.974(b)(3), an ambiguity exists with regard to the time frame for completing this type of reconsideration and escalation options when that time frame is not met. Current § 405.970 establishes the time frame for making a reconsideration without further qualification. However, section 1869(b)(1)(D)(i) of the Act establishes that a right to a reconsideration of an initial determination (which includes a redetermination under section 1869(a)(3)(D) of the Act) exists if a timely request for a reconsideration is filed within 180 days following receipt of a contractor's redetermination, which is discussed in § 405.962. In contrast, § 405.974(b)(1) requires that a request for a QIC reconsideration of a contractor's dismissal of a request for redetermination be filed within 60 calendar days after receiving the contractor's notice of dismissal. Section 1869 of the Act does not address dismissals. Rather, section 1869(c)(3)(C)(i) and (c)(3)(C)(ii) of the Act only provide for a time frame to complete a reconsideration of an initial determination, and an option to escalate a case if that time frame is not met.

The effect of the ambiguity in § 405.970 is the potential escalation of a request for a QIC reconsideration of a contractor's dismissal when the reconsideration is not completed within 60 calendar days of a timely filed request for a reconsideration of the dismissal, and a potential hearing being required in accordance with § 405.1002(b). The potential effect of this ambiguity is contrary to the policy of limiting reviews of dismissals to the next adjudicative level of administrative appeal, as well as the statutory construct for providing ALJ hearings after QIC reconsiderations of redeterminations, or escalations of requests for reconsiderations following a redetermination. We also note that in the parallel context of an ALJ review of

a QIC's dismissal of a request for reconsideration, §§ 405.1002 and 405.1004 establish a clear distinction between a request for hearing following a QIC reconsideration and a request for a review of a QIC dismissal, and §§ 405.1016 and 405.1104 address the adjudication time frames for ALJ decisions, and the option to escalate an appeal to the Council when a time frame is not met, only in the context of a request for hearing, in accordance with section 1869(d)(1) and (d)(3)(A) of the Act.

To address this unintended outcome of § 405.970, we proposed to amend the title of § 405.970 and paragraphs (a), (b)(1), (b)(2), (b)(3), (c), (e)(1), and (e)(2)(i) to provide that the provisions would only apply to a request for a reconsideration following a contractor redetermination, and not to a request for QIC review of a contractor's dismissal of a request for redetermination. We stated in the proposed rule that these revisions would further our policy on reviews of dismissals and help appellants better understand what may be escalated to OMHA for an ALJ hearing. We also proposed to replace "the ALJ hearing office" in current paragraph (e)(2)(ii) with "OMHA" because the QIC sends case files for escalated cases to a centralized location, not to individual field offices. We did not propose any parallel changes for part 423 because subpart U does not address IRE reconsiderations and subpart M does not have a provision with the same ambiguity. 81 FR 43790, 43799–43800.

To provide additional clarity to the procedures for reviews of dismissal actions, we also proposed to amend the text in §§ 405.972(b)(3), (e) and 405.974(b)(3), and the introductory text of § 405.974(b) to replace the references to a "reconsideration" of a contractor's dismissal of a request for redetermination with the word "review" so that the QIC's action is referred to as a review of a contractor's dismissal of a request for redetermination. We also proposed to revise the section heading of § 405.972 to read "Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination," and the section heading of § 405.974 to read, "Reconsideration and review of a contractor's dismissal of a request for redetermination." We stated in the proposed rule that these revisions are consistent with the description of a reconsideration in section 1869(c)(3)(B)(i) of the Act and § 405.968(a). As we stated in the proposed rule, a QIC's review of a contractor dismissal action is limited to

the appropriateness of the dismissal action and does not consist of a review of the initial determination and redetermination, which is the meaning attributed to a reconsideration. In reviewing a contractor dismissal action, the QIC either affirms or vacates the dismissal of the request for redetermination. If a dismissal action is vacated, the appeal is remanded back to the MAC to conduct a redetermination on the merits (§ 405.974). 81 FR 43790, 43800.

Current § 405.972(e) provides that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ under § 405.1004. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we proposed that an attorney adjudicator may conduct a review of a QIC's dismissal of a request for reconsideration and in section III.A.3.c of the proposed rule (discussed in section II.B.3.c of this final rule below), we proposed to revise § 405.1004 to provide the effect of an attorney adjudicator's action taken in reviewing the QIC dismissal is equivalent to the effect of an ALJ's action taken in reviewing the QIC dismissal. To align with our proposed revision to § 405.1004, we proposed to insert "or attorney adjudicator" after "an ALJ" in § 405.972(e) to indicate that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under § 405.1004. 81 FR 43790, 43800.

We received no comments on these proposals, other than: (1) Comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 405.970, 405.972, and 405.974 as proposed without modification.

#### j. Notice of Reconsideration (§ 405.976)

Section 1869(b)(3) of the Act states that a provider or supplier may not

introduce evidence in any appeal that was not presented at the reconsideration conducted by a QIC unless there is good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. Under this authority, § 405.976(b)(5)(ii) provides that a notice of reconsideration must include a summary of the rationale for the reconsideration that specifies that all evidence that is not submitted prior to the issuance of the reconsideration will not be considered at the ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration; however, it does not apply to a beneficiary unless the beneficiary is represented by a provider or supplier or to state Medicaid agencies. The statement that the evidence will not be made part of the administrative record is inconsistent with our practice of making a complete record of the administrative proceedings for further reviews, including documents submitted by parties that were not considered in making the decision. Current § 405.1028(c) states that if good cause does not exist, the ALJ must exclude the evidence from the proceedings and may not consider it in reaching a decision. However, it does not instruct the ALJ to remove the evidence from the administrative record, and to do so would preclude an effective review of the good cause determination. In addition, we noted in the 2005 Interim Final Rule (70 FR 11464) that under current § 405.1042(a)(2), excluded evidence is part of the record because it states that in the record, the ALJ must also discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. To help ensure that the evidence is preserved in the administrative record, we proposed to delete "or made part of the administrative record" from the paragraph in § 405.976(b)(5)(ii). 81 FR 43790, 43800.

Current § 405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. As further discussed in section III.A.3.d of the proposed rule and II.B.3.d of the final rule below, we proposed revisions to § 405.976(b)(7) along with revisions to the methodology for calculating the amount in controversy required for an ALJ hearing under § 405.1006(d) to better align the

amount in controversy with the actual amount in dispute. Please refer to section III.A.3.d of the proposed rule and II.B.3.d of this final rule below for a discussion of these proposals.

We did not propose any changes to part 423 because subpart U does not address IRE reconsiderations and subpart M does not contain similar provisions.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter requested that the notice of reconsideration contain language clarifying that good cause does not exist for a provider's submission of new evidence for the first time at the OMHA level, if the documentation was in the provider's possession during an audit that results in an initial determination.

*Response:* We appreciate the commenter's input, but believe the regulations as finalized in this rule clearly indicate that providers and suppliers should submit all evidence that is relevant to their appeal as early in the appeal process as possible, and the circumstances in which an ALJ or attorney adjudicator may find good cause for the introduction of new evidence at the OMHA level (see §§ 405.966(a)(2), 976(b)(5)(ii), 405.1018, 405.1028, and 405.1030). We understand that appellants may not always know which documents are necessary to support their appeal. To assist appellants, contractors issuing redetermination notices are instructed at § 405.956(b)(6) to identify "specific missing documentation," that should be submitted with the request for reconsideration. We encourage appellants to submit any and all evidence that may help with their appeal before the OMHA level. Section 405.1018 requires a provider, supplier, or a beneficiary represented by a provider or supplier, that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. We also believe the regulations, as finalized in this rule, clearly set forth the consequences for not showing good cause. We proposed that § 405.1018(c)(2) be added to state that if the provider or supplier, or beneficiary represented by a provider or supplier, fails to include the statement explaining why the evidence was not previously submitted, the evidence will not be considered. To strengthen the existing requirement for the full and early presentation of evidence, we are finalizing our proposed changes at

§ 405.1018(c)(2), as discussed in section II.B.3.i below.

We proposed at § 405.1028(a)(2)(i) through (v) to include specific instances when an ALJ or attorney adjudicator may find good cause for the introduction of new evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is submitted for the first time at the OMHA level, but the ultimate finding of whether there is good cause under these provisions would be at the discretion of the ALJ or attorney adjudicator. We believe that the proposed changes to § 405.1028 that we are adopting provide sufficient guidance regarding the circumstances in which an ALJ or attorney adjudicator may find good cause, and thus we do not believe it is necessary to include the commenter's requested revision in the notice of reconsideration. As explained above (and discussed in section III.A.2.j of the proposed rule), the proposed change to the notice of reconsideration at § 405.976(b)(5)(ii) was intended to reflect that evidence submitted after the reconsideration that does not meet the good cause standard will still be preserved in the administrative record, as the statement in § 405.976(b)(5)(ii) that the evidence would not be made part of the administrative record was inconsistent with current practice of making a complete record of the administrative proceedings for further review. In our ongoing effort to streamline the Medicare Appeals process, we encourage appellants to submit evidence as early on in the appeals process as possible, but do not believe the commenter's suggested revision is necessary to accomplish this goal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing without modification this change to § 405.976(b)(5)(ii) as proposed.

#### k. Effect of a Reconsideration (§ 405.978)

Section 405.978 discusses the effect of a QIC reconsideration, and states that a reconsideration is binding on all parties unless, among other things, an ALJ decision is issued in accordance with a request for an ALJ hearing made in accordance with § 405.1014. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we proposed that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted, and in section III.A.3.v of the proposed rule (as discussed in section II.B.3.v of this final rule below), we proposed to revise

§ 405.1048 to provide the effect of an attorney adjudicator's decision is equivalent to the effect of an ALJ's decision. To align with our proposals to provide that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted and the effect of that decision is equivalent to the effect of an ALJ's decision, we proposed to insert "or attorney adjudicator" after the first use of "ALJ" in § 405.978(a) to indicate that a QIC reconsideration is binding on all parties unless, among other things, an ALJ or attorney adjudicator decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014. 81 FR 43790, 43800–43801.

We received no comments on this proposal, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing this change to § 405.978 as proposed without modification.

l. Reopenings (§§ 405.980, 405.982, 405.984, 423.1978, 423.1980, 423.1982, and 423.1984)

As discussed below, we proposed a number of revisions to the rules governing reopening and revision of initial determinations and appeal decisions. 81 FR 43790, 43801. Sections 405.980 and 423.1980 set forth the rules governing reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews; §§ 405.982 and 423.1982 set forth the rules governing notice of a revised determination or decision; and §§ 405.984 and 423.1984 set forth the rules on the effect of a revised determination or decision. Pursuant to §§ 405.1038 and 423.2038, an ALJ may issue a decision on a request for hearing without conducting a hearing in specified circumstances. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney adjudicator also would be able to issue decisions on requests for an ALJ hearing in specified circumstances, issue dismissals when a party withdraws a request for hearing, and issue decisions on requests to review QIC or IRE dismissals.

We proposed to insert "or attorney adjudicator" or "attorney adjudicator's," after "ALJ" or "ALJ's" in

§§ 405.980(a)(1)(iii), (a)(4), (a)(5), (d) introductory text, (d)(2), (e)(2); 405.982(a), (b); 405.984(d); 423.1980(a)(1)(iii), (a)(4), (d) introductory text, (d)(2), (e)(2); 423.1982(a), (a)(1), (a)(2), (b), (b)(1), and (b)(2); 423.1984(d); 423.1978(a); 423.1980(a)(2). We stated in the proposed rule that these revisions would provide that decisions issued by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), may be reopened in the same manner as decisions issued by an ALJ (that is, when there is good cause in accordance with §§ 405.986 or 423.1986, or the decision was procured by fraud or similar fault), and with the same limitations, requirements, and effects as reopening an ALJ decision. We stated in the proposed rule that we believe it is necessary for an attorney adjudicator or the Council to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ or the Council may reopen the ALJ's decision under the current rules; to address instances in which there is good cause to reopen the attorney adjudicator's decision (in accordance with §§ 405.986 or 423.1986) or the attorney adjudicator's decision was procured by fraud or similar fault; and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under the provisions.

We also proposed to replace "hearing decision," "hearing decisions," or "hearings," with "decision" or "decisions" in the titles of §§ 405.980 and 423.1980; §§ 405.980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); 423.1980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); to replace "hearing" with "ALJ or attorney adjudicator decision" in §§ 405.980(a)(1)(iv), (a)(4), (e)(2); 423.1980(a)(1)(iv), (a)(2), and (e)(2); and to replace "ALJ hearing decisions" and "hearing decision," with "ALJ or attorney adjudicator decisions" and "ALJ or attorney adjudicator decision", respectively, in §§ 405.984(d) and 423.1984(d). We stated in the proposed rule that these revisions would avoid any confusion that reopening under these provisions is limited to decisions for which an oral hearing was conducted, whether the decision is issued by an ALJ without conducting a hearing, as permitted under current rules or by an attorney adjudicator without conducting a hearing, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above).

In addition, we proposed to add in §§ 405.980(a)(1)(iii), (d)(2), (e)(2), and 423.1980(a)(1)(iii), (d)(2), (e)(2) that an ALJ, or attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), revises "his or her" decision and may reopen "his or her" decision, which reflects our current policy that the deciding ALJ may reopen his or her decision, and avoids any potential confusion that an ALJ or attorney adjudicator may reopen the decision of another ALJ or attorney adjudicator. We also proposed to insert "its" before "review" in §§ 405.980(a)(1)(iv) and 423.1980(a)(1)(iv) to indicate that the Council's review decision may only be reopened by the Council, to differentiate it from an ALJ or attorney adjudicator decision that the Council may also reopen. In addition, we proposed to specify in §§ 405.980(d)(2) and (e)(2), and 423.1980(d)(2) and (e)(2) that the Council may reopen "an ALJ or attorney adjudicator" decision consistent with the current policy that the Council may reopen an ALJ decision, and to differentiate the provisions from §§ 405.980(d)(3) and (e)(3), and 423.1980(d)(3) and (e)(3), which provide for the Council to reopen its review decision. We also proposed in § 405.980(e)(3) to insert "Council" before "review" to clarify that a party to a Council review may request that the Council reopen its decision.

Finally, we proposed at § 405.984(c) to replace "in accordance with § 405.1000 through § 405.1064" with "in accordance with § 405.1000 through § 405.1063" to account for the proposed removal of § 405.1064 discussed below.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing our proposals as discussed above, without modification, to revise the rules governing the reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

m. Expedited Access to Judicial Review (§§ 405.990 and 423.1990)

Sections 405.990 and 423.1990 set forth the procedures governing

expedited access to judicial review (EAJR). Current §§ 405.990(d) and 423.1990(d) allow a requesting party to file an EAJR request with an ALJ or the Council, which is then responsible for forwarding the request to the EAJR review entity within 5 calendar days of receipt. In accordance with §§ 405.990(f) and 423.1990(e), a request for EAJR must be acted upon by the EAJR review entity within 60 calendar days after the date that the review entity receives a request and accompanying documents and materials. In practice, this process has resulted in confusion and delays for requesting parties when EAJR requests are sent directly to an ALJ or the Council. To simplify the process for requesting parties and to help ensure the timely processing of EAJR requests, we proposed to revise §§ 405.990(d)(1) and 423.1990(d)(1) to direct EAJR requests to the DAB, which administers the EAJR process. Specifically, we proposed at §§ 405.990(d)(1)(i) and (ii), and 423.1990(d)(1)(i) and (ii) that the requestor or enrollee may file a written EAJR request with the DAB with the request for ALJ hearing or Council review if a request for ALJ hearing or Council review is not pending, or file a written EAJR request with the DAB if an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council. We also proposed to revise §§ 405.990(i)(1) and (2) and 423.1990(h)(1) and (2) so that the review entity would forward a rejected EAJR request to OMHA or the Council instead of an ALJ hearing office or the Council, to align with the revised EAJR filing process in which a request for ALJ hearing is submitted to the DAB with an EAJR request; we stated that this would also help ensure OMHA can process the request for an ALJ hearing as quickly as possible in the event an EAJR request is rejected.

Sections 405.990(i)(2) and 423.1990(h)(2) provide that a 90 calendar day time frame will apply to an appeal when a rejected EAJR request is received by the hearing office or the Council. Section 405.990(b)(1)(ii) states that an EAJR request may be filed when a request for a QIC reconsideration has been escalated for an ALJ hearing, and in accordance with current § 405.1016(c), a 180 calendar day time frame will apply in that circumstance. In addition, §§ 405.1036(d) and 423.2036(d) allow an appellant or enrollee to waive the adjudication period for an ALJ to issue a decision specified in §§ 405.1016 and 405.2016, respectively, at any time during the hearing process. To address the possibility that a time frame other than



90 calendar days applies to an appeal, or no adjudication time frame applies to an appeal, we proposed to revise §§ 405.990(i)(2) and 423.1990(h)(2) to remove the reference to 90 calendar days and provide that if an adjudication time frame applies to an appeal, the adjudication time frame begins on the day the request for hearing is received by OMHA or the request for review is received by the Council, from the EAJR review entity.

In addition, we proposed at § 405.990(i)(1) to remove the redundant “request” after “EAJR request” in current paragraph (i)(1), which was a drafting error; and at § 423.1990(b)(1)(i) to remove “final” before referring to a decision, dismissal, or remand order of the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), because as we explained in the 2009 Final Rule (74 FR 65307 through 65308), final decisions of the Secretary are those for which judicial review may be immediately sought under section 205(g) of the Act and the use of “final” in current § 423.1990(b)(1)(i) may cause confusion with such a final decision.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 405.990 and 423.1990 as proposed without modification.

### 3. ALJ hearings

#### a. Hearing Before an ALJ and Decision by an ALJ and Attorney Adjudicator: General Rule (§§ 405.1000 and 423.2000)

As described below, we proposed a number of revisions to §§ 405.1000 and 423.2000, which provide a general overview and rules for hearings before an ALJ and decisions on requests for hearings. 81 FR 43790, 43802–43803. We proposed to revise §§ 405.1000(d), (e), (g); and 423.2000(d), (e), (g) to

include decisions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to retitle the sections to reflect that the provisions of the section extend to decisions by both ALJ and attorney adjudicators. We proposed to change the language in §§ 405.1000(a), (b), (c), and (d); and 423.2000(a) and (b) to state that a hearing may only be conducted by an ALJ. We stated in the proposed rule that these revisions would provide readers with an accurate overview of how a request for an ALJ hearing would be adjudicated, including the potential that a decision could be issued without conducting a hearing by an ALJ or an attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), while informing readers that if a hearing is conducted, an ALJ will conduct the hearing.

Section 405.1000(c) provides that CMS or a contractor may elect to participate in a hearing, and § 423.2000(c) provides that CMS, the IRE or Part D plan sponsor may request to participate in a hearing. As discussed in section III.A.3.f of the proposed rule and II.B.3.f of this final rule below, we proposed to revise §§ 405.1010 and 423.2010 so that these entities may elect (for § 405.1010) or request (for § 423.2010) to participate in the proceedings on a request for hearing, including participation before a hearing is scheduled. We proposed to revise §§ 405.1000(c) and 423.2000(c) so that the sections would reference §§ 405.1010 and 423.2010, respectively, with regard to participating in the proceedings. We stated in the proposed rule that by referencing §§ 405.1010 and 423.2010, the proposed revisions would direct readers to those sections addressing the full scope of potential participation by CMS or its contractors, or a Part D plan sponsor, on a request for an ALJ hearing, including participating in the proceedings on a request for an ALJ hearing, which as discussed in proposed §§ 405.1010 and 423.2010, may include any proceedings before an oral hearing is scheduled. We also proposed in § 405.1000(c) to state that CMS or its contractor may join the hearing before an ALJ as a party under § 405.1012, which would direct readers to the appropriate section addressing the full scope of CMS or its contractor acting as a party. (Because CMS, the IRE, and the Part D plan sponsor may not be a party to a hearing under part 423, subpart U, there is no corollary to § 405.1012 in that subpart and therefore

a similar revision was not proposed for § 423.2000(c).)

Sections 405.1000(d) and 423.2000(d) provide that a decision is based on the hearing record, and §§ 405.1000(g) and 423.2000(g) reference a hearing record in describing when a decision can be issued based on the record, without a hearing. However, §§ 405.1042 and 423.2042 identify the record as the administrative record. We stated in the proposed rule that the references to a hearing record in paragraphs (d) and (g) may cause confusion when no hearing is conducted. To make the terminology consistent throughout the rules, account for decisions that are issued without a hearing being conducted, and minimize confusion, we proposed to revise §§ 405.1000(d) and 423.2000(d) so that a decision is based on the administrative record, including, for an ALJ, any hearing record, and §§ 405.1000(g) and 423.2000(g) to provide that a decision is based on the administrative record.

Section 405.1000(e) and (g) discuss two circumstances in which a decision on a request for hearing can be issued by an ALJ without conducting a hearing, either where the parties waive the hearing or where the record supports a fully favorable finding. Related to § 405.1000(e), § 405.1000(f) discusses the ALJ's authority to conduct a hearing even if the parties waive the hearing. As discussed in section III.A.3.r of the proposed rule and II.B.3.r of this final rule below, we proposed to revise § 405.1038 to modify the circumstances in which a decision on a request for hearing can be issued without conducting a hearing. As discussed in the proposed revisions to § 405.1038, we proposed in § 405.1038 that a case could be decided without a hearing before an ALJ if: (1) waivers are obtained by the parties entitled to a notice of hearing in accordance with § 405.1020(c) (§ 405.1038(b)(1)(i)); or (2) the record supports a fully favorable finding for the appellant on every issue and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing (§ 405.1038(a)). We proposed to revise § 405.1000(e), (f), and (g) for consistency with the § 405.1038 proposals and to accurately summarize when a decision on a request for hearing can be issued without conducting a hearing in accordance with proposed § 405.1038. We did not propose similar changes in § 423.2000(e), (f), and (g) because we did not propose changes to when a decision on a request for hearing can be issued without conducting a hearing in § 423.2038.

Current § 405.964(c) requires a QIC to consolidate requests for a

reconsideration filed by different parties on the same claim before a reconsideration is made on the first timely filed request. While current § 405.1044 permits an ALJ to consolidate requests for hearing if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing pending before the same ALJ, the provision is discretionary and dependent on the requests being assigned to the same ALJ. To mitigate the potential of requests for hearing on the same claim filed by different parties being separately adjudicated, we proposed to add § 405.1000(h) to require that when more than one party files a timely request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued. We noted in the proposed rule that if a decision was issued on the first timely request before an additional request is timely filed or good cause is found to extend the period to file the additional request for hearing, a reopening of the decision could be considered by the deciding adjudicator in accordance with § 405.980. For example, we stated that if a request is submitted with new and material evidence that was not available at the time of the decision and may result in a different conclusion, the reopening provisions at § 405.980 would apply. Because only the enrollee is a party in a part 423, subpart U proceeding on a request for an ALJ hearing, no corresponding changes were proposed for § 423.2000.

Provided below are summaries of the specific comment received and response to the comment:

*Comment:* We received one comment on these proposals. The commenter strongly supported our proposal to revise § 405.1000(e), (f), and (g) for consistency with our § 405.1038 proposals which, among other things, would preclude an ALJ from issuing a fully favorable decision on the record if CMS or a CMS contractor has elected to be a party to the hearing in accordance with § 405.1012. The commenter stated that when audit contractors have an opportunity to present their findings, it helps ensure that ALJ decisions reflect a fuller understanding of the circumstances.

*Response:* We thank the commenter for its support. As the commenter indicated, we proposed to revise § 405.1000(e), (f), and (g) for consistency with proposed § 405.1038. However, we note that we inadvertently included language in proposed § 405.1000(g) that

is not consistent with the language in proposed § 405.1038(a) (relating to fully favorable decisions issued on the record). Proposed § 405.1000(g) states that an ALJ or attorney adjudicator may issue a decision on the record if the evidence in the administrative record supports a fully favorable finding for the appellant, “and there is no other party or no other party is entitled to a notice of hearing in accordance with § 405.1020(c).” However, proposed § 405.1038(a) states that an ALJ or attorney adjudicator may issue a decision without an ALJ conducting a hearing if the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue “and no other party to the appeal is liable for the claims at issue . . . unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.” Thus, consistent with our proposal to revise § 405.1000(g) for consistency with § 405.1038(a), in this final rule, we are revising the language in § 405.1000(g) to be consistent with the language of § 405.1038(a) as finalized in this rule. We are revising § 405.1000(g) to state that, “An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.”

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, and in section II.B.3.r below concerning § 405.1038 (which also explains the circumstances in which a decision on a request for hearing can be issued without conducting a hearing), we are finalizing §§ 405.1000 and 423.2000 as proposed with the modifications discussed above.

**b. Right to an ALJ Hearing (§§ 405.1002 and 423.2002)**

As discussed below, we proposed a number of revisions to §§ 405.1002 and 423.2002, which discuss a right to an ALJ hearing. 81 FR 43790, 43803. Current §§ 405.1002(a) and 423.2002(a) provide that a party to a QIC reconsideration or the enrollee who receives an IRE reconsideration, respectively, may “request” a hearing before an ALJ if the party or enrollee files a timely request and meets the amount in controversy requirement. However, a party or enrollee is entitled to a hearing only when those requirements are met. See sections

1860D–4(h) and 1869(b)(1)(A) of the Act. Therefore, we proposed to revise §§ 405.1002(a) and 423.2002(a) introductory text to state that the party to a QIC reconsideration or the enrollee who receives an IRE reconsideration has a right to a hearing rather than may request a hearing. These revisions would align the provisions with the statute and clarify that the party or enrollee has a right to a hearing before an ALJ when the criteria are met.

Current §§ 405.1002(a)(4) and 423.2002(e) provide that the request is considered filed on the date it is received by the entity specified in the QIC’s or IRE’s reconsideration. There has been confusion when a request is sent to an OMHA office that is not specified in the reconsideration, and this error causes delays in processing the request. We proposed to revise §§ 405.1002(a)(4) and 423.2002(e) to replace “entity” with “office” to avoid confusion that the request may be filed with OMHA as an entity, and therefore any OMHA office, rather than the specific OMHA office identified in the QIC’s or IRE’s reconsideration. We stated in the proposed rule that this would help ensure appellants are aware that a request for hearing must be filed with the office indicated in the notice of reconsideration to avoid delays. For example, when the notice of reconsideration indicates that a request for hearing must be filed with the OMHA central docketing office, an appellant will cause a delay if the request is sent to the QIC or IRE, or an OMHA field office. We also noted in the proposed rule that as explained in the 2009 Final Rule (74 FR 65319 through 65320), pursuant to current § 405.1014(b)(2), if a request for hearing is timely filed with an entity other than the entity specified in the notice of reconsideration, the request is not treated as untimely or otherwise rejected. We stated that this would remain true for requests that are timely filed with an office other than the office specified in the notice of reconsideration, pursuant to proposed § 405.1014(c)(2), which incorporates the requirement from current § 405.1014(b)(2). This would also apply in part 423, subpart U adjudications because the same language appears in current § 423.2014(c)(2) and is incorporated in proposed § 423.2014(d)(2).

Current § 405.1002(b)(1) provides that when a party files a request with the QIC to escalate the appeal, it is escalated to “the ALJ level.” We proposed to revise § 405.1002(b)(1) to replace “to the ALJ level” with “for a hearing before an ALJ” so that when a request for a QIC

reconsideration is escalated, it is escalated “for a hearing before an ALJ.” We stated in the proposed rule that this would help ensure that the right to a hearing is clear when an appeal is escalated from the QIC. There is no corresponding provision in part 423, subpart U.

Current § 423.2002(c) provides that the ALJ must document all oral requests for expedited hearings. However, an ALJ is not assigned to an appeal until after the request for hearing is received and processed. Thus, we proposed to revise § 423.2002(c) to state that “OMHA” must document all oral requests for expedited hearings. There is no corresponding provision in part 405, subpart I.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Two commenters generally supported the proposal to replace “entity” with “office” in proposed §§ 405.1002(a)(4) and 423.2002(e), but expressed concern that beneficiaries may nevertheless continue to send requests for hearing to the wrong entity or office. The commenters therefore urged OMHA to continue its policy of accepting requests that are timely filed with the wrong entity or office, and to incorporate this policy in regulation.

*Response:* As we explained in section III.A.3.g.iv of the proposed rule (and discussed in section II.B.3.g.iv below), §§ 405.1014(b)(2) and 423.2014(c)(2)(i) state that if a request for hearing is timely filed with an entity other than the entity specified in the QIC’s or IRE’s reconsideration, the deadline specified in § 405.1016 or § 423.2016 for deciding the appeal begins on the date the entity specified in the QIC’s or IRE’s reconsideration receives the request for hearing. We proposed to incorporate portions of §§ 405.1014(b)(2) and 423.2014(c)(2)(i) in proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i), respectively, but to replace “entity” with “office” in both sections (to help ensure appellants are aware that a request for hearing or request for review of a QIC or IRE dismissal must be filed with the office indicated in the QIC’s or IRE’s notice of reconsideration or dismissal in order to avoid delays) and “submitted” with “filed” in § 423.2014(d)(1) (for consistency with § 405.1014 and § 422.602). We also noted above and in section III.A.3.b and section III.A.3.g.iv of the proposed rule (discussed in section II.B.3.g.iv below) that, for those few requests for hearing that are misrouted by a party, the date the request for hearing was received in the incorrect office would be used to determine the timeliness of the request,

as explained in the 2009 Final Rule (74 FR 65319 through 65320).

We agree with the commenter that OMHA’s policy of not treating as untimely a request for an ALJ hearing that is timely filed with an office other than the office specified in the QIC’s or IRE’s reconsideration should be expressly stated in the regulation. Thus, as discussed in section II.B.3.g.iv below, we are finalizing the additional language in proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that, if the request for hearing is timely filed with an office other than the office specified in the QIC’s reconsideration, the request is not treated as untimely.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 405.1002 and 423.2002 as proposed without modification. In addition, as discussed above and in section II.B.3.g.iv below, we are adding language in §§ 405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that, if the request for hearing is timely filed with an office other than the office specified in the QIC’s reconsideration, the request is not treated as untimely.

#### c. Right to a Review of QIC or IRE Notice of Dismissal (§§ 405.1004 and 423.2004)

As discussed below, we proposed several revisions to §§ 405.1004 and 423.2004, which discuss the right to an ALJ review of a QIC notice of dismissal or IRE notice of dismissal, respectively. 81 FR 43790, 43803–43804. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), attorney adjudicators or ALJs would conduct reviews of QIC or IRE dismissals. Accordingly, we proposed to remove references to an ALJ in the titles of proposed §§ 405.1004 and 423.2004, though ALJs would continue to have the authority to conduct reviews of QIC or IRE dismissals if a request for a review of a QIC or IRE dismissal is assigned to an ALJ. We also proposed to insert “or attorney adjudicator” after ALJ in §§ 405.1004(a) introductory language, (b), (c); and 423.2004(a) introductory language, (b), and (c), to provide that an attorney adjudicator could review a QIC or IRE dismissal, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to replace the reference to “entity” in current §§ 405.1004(a)(4) and 423.2004(a)(4), with “office,” for the same reasons discussed in III.A.3.b of the proposed rule and II.B.3.b of this final rule above, for amending parallel language in §§ 405.1002 and 423.2002.

Current §§ 405.1004(b) and 423.2004(b) provide that if an ALJ determines that the QIC’s or IRE’s dismissal was in error, he or she vacates the dismissal and remands the case to a QIC or IRE. As discussed in III.A.3.p of the proposed rule and II.B.3.p of this final rule below, we proposed to revise the remand provisions and add new §§ 405.1056 and 405.1058, 423.2056, and 423.2058 to govern when remands may be issued, whether and to what extent remands may be reviewed, providing notice of a remand, and the effect of a remand. We also proposed to revise §§ 405.1004(b) and 423.2004(b) to add references to proposed §§ 405.1056 and 423.2056, respectively, to explain that the remand would be in accordance with proposed §§ 405.1056 and 423.2056, which as discussed in section III.A.3.p of the proposed rule and II.B.3.p of this final rule below, would address issuing remands and notices thereof, including for remands of QIC or IRE dismissals.

Current §§ 405.1004(c) and 423.2004(c) state that an ALJ’s decision regarding a QIC’s or IRE’s dismissal of a reconsideration request is binding and not subject to further review, and that the dismissal of a request for ALJ review of a QIC’s or IRE’s dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the Council under § 405.1108(h) or § 423.2108(b), respectively. In our experience, these sections as currently drafted have been a source of confusion for adjudicators and appellants. The two sentences convey different actions that can result from a request for review of a QIC or IRE dismissal—a decision regarding whether the QIC’s or IRE’s dismissal was correct, or a dismissal of the appellant’s request for an ALJ review of the QIC’s or IRE’s dismissal. We proposed to separate and further distinguish the two situations to avoid the current confusion that results from two of the three possible outcomes that may result from a request to review a QIC or IRE dismissal (the third being a remand of the dismissal, addressed in paragraph (b) in the respective sections) being in the same paragraph by proposing a separate paragraph for each outcome currently addressed in paragraph (c).

We proposed to revise §§ 405.1004(c) and 423.2004(c) to include the possible outcome in the first sentence of current §§ 405.1004(c) and 423.2004(c) of a decision affirming the QIC’s or IRE’s dismissal. We also proposed to move language in current §§ 405.1004(c) and 423.2004(c) stating that the decision of an ALJ on a request for review of a QIC dismissal is binding and not subject to

further review, to proposed §§ 405.1048(b) and 423.2048(b), which as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below, would address the effects of decisions on requests to review a QIC or IRE dismissal. In addition, we proposed in §§ 405.1004(c) and 423.2004(c), respectively, to state that a decision affirming a QIC or IRE dismissal would be issued in accordance with proposed §§ 405.1046(b) and 423.2046(b), which as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below, would address issuing decisions on requests for review of a QIC or IRE dismissal and notices thereof.

The 2009 Final Rule (74 FR 65311 through 65312) also explained that if a request for ALJ review of a QIC dismissal was invalid and thus subject to dismissal, the dismissal of the request to review a QIC dismissal was binding and not subject to further review (however, a party could request that the dismissal be vacated by the Council pursuant to § 405.1108(b)). We proposed to add §§ 405.1004(d) and 423.2004(d) to state that the ALJ or attorney adjudicator may dismiss a request for review of a QIC's or an IRE's dismissal in accordance with proposed §§ 405.1052(b) or 423.2052(b), respectively, which as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule below, would address dismissals of requests for review of a QIC or IRE dismissal and notices thereof. We also proposed to move language in current §§ 405.1004(c) and 423.2004(c) stating that the dismissal is binding and not subject to further review unless the dismissal is vacated, to proposed §§ 405.1054(b) and 423.2054(b), which would address the effects of a dismissal of a request for review of a QIC's or an IRE's dismissal and as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule below, would provide authority for an ALJ or attorney adjudicator to vacate a dismissal and therefore replace the current reference to the Council.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these

changes to §§ 405.1004 and 423.2004 as proposed without modification.

d. Amount in Controversy Required for an ALJ Hearing (§§ 405.976, 405.1006, 422.600, 423.1970, and 478.44)

As described below, we proposed a number of changes to the amount in controversy provisions in §§ 405.1006, 423.1970, and 478.44, as well as an associated change to § 405.976(b)(7) regarding the content of a QIC's notice of reconsideration. 81 FR 43790, 43804–43810, 43854. Current § 405.1006 sets forth the requirements for meeting the amount in controversy for an ALJ hearing. The title of current § 405.1006 states that the amount in controversy is required to “request” an ALJ hearing and judicial review. However, as discussed in III.A.3.b of the proposed rule and II.B.3.b of this final rule above, section 1869(b)(1)(A) of the Act states that a party is entitled to a hearing before the Secretary and judicial review, subject to the amount in controversy and other requirements. To align the title of § 405.1006 with the statutory provision, we proposed that the amount in controversy is required “for” an ALJ hearing and judicial review rather than “to request” an ALJ hearing and judicial review. Put another way, a party may request an ALJ hearing or judicial review, albeit unsuccessfully, without satisfying the amount in controversy requirement.

Section 1869(b)(1)(E) of the Act establishes the minimum amounts in controversy for a hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy. Current § 405.1006(d) states that the amount remaining in controversy is calculated based on the actual amount charged to the individual (a beneficiary) for the items or services in question (commonly referred to as billed charges), reduced by any Medicare payments already made or awarded for the items or services, and any deductible and coinsurance amounts applicable to the particular case. In an effort to align the amount in controversy with a better approximation of the amount at issue in an appeal, we proposed to revise the basis (that is, the starting point before any deductions for any payments already made by Medicare or any coinsurance or deductible that may be collected) used to calculate the amount in controversy. For appeals of claims submitted by providers of services, physicians, and other suppliers that are priced based on a published Medicare fee schedule or published contractor-priced amount (as discussed below), rather than using the actual amount charged to the individual

as the basis for the amount in controversy, we proposed to use the Medicare allowable amount for the items and/or services being appealed, subject to the exceptions discussed below. An allowable amount is the maximum amount of the billed charge deemed payable for the item or service. For the purposes of the amount in controversy under § 405.1006, we proposed at § 405.1006(d)(2)(i)(A) that for items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy would be the allowable amount, which would be the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service.

We stated in the proposed rule that for a vast majority of items and services furnished and billed by physicians and other suppliers, allowable amounts are determined based on Medicare fee schedules. Fee schedules generally are updated and published on an annual basis by CMS through rulemaking, and CMS and its contractors have tools and resources available to inform physicians and other suppliers of allowable amounts based on these fee schedules, including the Physician Fee Schedule Look-up Tool available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/> and spreadsheets for other fee schedules that can be accessed on the CMS Web site through the fee schedule main page at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html>. Allowable amounts for many contractor-priced items and services are also included in these tools and resources. Allowable amounts are included on the Medicare remittance advice for paid items and services, but not for items and services that are denied. However, where the allowable amount for an item or service is determined based on a published fee schedule or contractor-priced amount, we stated that we anticipated that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, would be able to use the existing CMS and contractor tools and resources to determine allowable amounts for denied services when filing a request for hearing, and those amounts could be verified by OMHA in determining whether the claims included in the request meet the amount in controversy requirement. As discussed below, where the appellant is a beneficiary who is not represented by a provider, supplier, or Medicaid State

agency, we proposed that CMS would require the QIC to specify in the notice of reconsideration, for partially or fully unfavorable reconsideration decisions, whether the amount remaining in controversy is estimated to meet or not meet the amount required for an ALJ hearing under proposed § 405.1006(d).

We stated in the proposed rule that, due to the pricing methodology for many items and services furnished by providers of services, such as hospitals, hospices, home health agencies, and skilled nursing facilities, at the present time an allowable amount is not easily discerned or verified with existing CMS and contractor pricing tools (for example, there is no pricing tool available for hospital outpatient services paid under the outpatient prospective payment system (OPPS)) for pre-payment claim denials (where items or services on the claim are denied, in full or in part, before claim payment has been made). Similarly, we stated that items and services furnished by providers or suppliers that are always non-covered, as well as unlisted procedures, may not have published allowable amounts based on a fee schedule or a published contractor-priced amount. Therefore, we proposed at § 405.1006(d)(2)(i)(B) to continue using the provider's or supplier's billed charges as the basis for calculating the amount in controversy for appeals of claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (except as discussed below). We noted that the method for calculating the amount in controversy in this scenario would be the same as under current § 405.1006(d), and we stated that we believe that all appellants have access to this information through claims billing histories, remittance advices, or the column titled "Amount Provider [or Supplier] Charged" on the Medicare Summary Notice. However, we solicited comment on whether existing tools and resources are available that would enable providers, suppliers, and Medicaid State agencies to submit an allowable amount in their request for hearing, as proposed in section III.A.3.g.i of the proposed rule (and discussed in section II.B.3.g.i below) for items and services not subject to published fee schedules or published contractor-priced amounts, and whether those amounts could also be verified by OMHA. We also solicited comment on how such tools and resources could be used in appeals filed by beneficiaries.

Current § 405.1006(d)(1) introductory text uses "the actual amount charged the individual for the items and services in question" as the basis (starting point)

for calculating the amount in controversy, before any reductions described in paragraphs (d)(1)(i) and (ii) (for any Medicare payments already made or awarded and any deductible and coinsurance applicable in the particular case) occur. For the reasons discussed above, we proposed to revise paragraph (d)(1) introductory text to state that in situations other than those described in § 405.1006(d)(3) through (7) (discussed below), the amount in controversy is computed as "the basis for the amount in controversy for the items and services in the disputed claim as defined in paragraph (d)(2)", less applicable reductions described in paragraphs (d)(1)(i) and (ii), and proposed to revise paragraph (d)(2) to specify the amount that would be used as the basis for the amount in controversy on a situational basis. We also proposed at § 405.1006(d)(3) through (7) five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

There has also been confusion in calculating the amount in controversy when an appealed reconsideration involves multiple claims. Section 1869 of the Act and part 405, subpart I provide for an appeals process in which each claim decision is appealed and separately adjudicated. However, in some instances, claims are considered together based on an appellant's request. To address confusion with calculating the amount in controversy when reconsiderations involve multiple claims and to help ensure § 405.1006 clearly conveys that the amount in controversy requirement must be met for each appealed claim unless the claim can be aggregated as discussed below, we proposed in § 405.1006(d)(1) to clarify that the amount in controversy is based on the items or services in the disputed "claim."

We proposed to maintain the current reduction to the calculation of the amount in controversy in § 405.1006(d)(1)(i), which states that the basis for the amount in controversy is reduced by any Medicare payments already made or awarded for the items or services. In addition, current § 405.1006(d)(1)(ii) provides that the basis for the amount in controversy is further reduced by "[a]ny deductible and coinsurance amounts applicable in the particular case." We proposed to revise § 405.1006(d)(1)(ii) to read, "Any deductible and/or coinsurance amounts that may be collected for the items or services." We stated in the proposed rule that we believe revising this provision is appropriate to better align the amount at issue in the appeal and

the amount in controversy so that in situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible, or must refund any such amounts already collected, the basis for the amount in controversy is not reduced by that amount (for example, if a provider or supplier is held liable for denied services under the limitation on liability provision in section 1879 of the Act, any amounts collected for the denied service, including coinsurance and/or deductible must be refunded).

As discussed above, we proposed at § 405.1006(d)(2)(i) that, for situations other than those described in § 405.1006(d)(2)(ii) and (iii), the basis for calculating the amount in controversy under § 405.1006(d)(1) would be the Medicare allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service if there is a published Medicare fee schedule or published contractor-priced amount for the items or services in the disputed claim; or if there is no published Medicare fee schedule or contractor-priced amount for the items or services in the disputed claim, the basis for the amount in controversy would be the provider or supplier's billed charges submitted on the claim for the items and services. We stated that we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS and CMS contractor tools and resources to determine the allowable amount for items and services with published fee schedule or published contractor-priced amounts, and for items or services without a published fee schedule or published contractor-priced amount, the calculation methodology for the amount in controversy would be the same as the calculation methodology specified in current § 405.1006(d). However, we stated there may be instances where a beneficiary would appeal a claim for items and services for which the allowable amount would be the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) (for example, a claim for items or services with a published fee schedule or published contractor-priced amount that does not involve an overpayment and for which the beneficiary has not been determined to be financially responsible). We stated that we believe most beneficiaries are not familiar with published fee schedule or contractor-priced amounts and may be unable to determine the amount in controversy in

these circumstances with the resources currently available to them. However, as discussed below, we proposed at § 405.976(b)(7) that the QIC include in the notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable to the appellant. For appeals filed by beneficiaries, often the amount at issue is aligned not with the Medicare allowable amount, but rather with the billed charges of the provider or supplier. For example, where a beneficiary is held financially responsible for a denied claim under the limitation on liability provisions in section 1879 of the Act because he or she received an Advance Beneficiary Notice of Noncoverage (ABN), the beneficiary is responsible for the billed charges on the claim. Or, for a claim not submitted on an assignment-related basis that is denied, the beneficiary may be responsible for the billed charges, or the billed charges subject to the limiting charge in section 1848(g) of the Act. Medicare notifies the beneficiary of the amount he or she may be billed for denied services on the Medicare Summary Notice in a column titled, "Maximum You May Be Billed." For appeals filed by a provider, supplier, or Medicaid State agency for denied items or services for which the beneficiary was determined to be financially responsible, we stated in the proposed rule that we believed providers, suppliers, and Medicaid State agencies would have sufficient access to the provider or supplier's billing information and Medicare claims processing data to determine the amount charged to the beneficiary. Accordingly, we proposed at § 405.1006(d)(2)(ii) that for any items or services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been received) for the items or services in the disputed claim. As discussed above, this amount would be set forth on the Medicare Summary Notice in the column titled "Maximum You May Be Billed."

We also proposed at § 405.1006(d)(2)(iii) that if a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the

items or services in the disputed claim under applicable statutory or regulatory authorities, the basis for the amount in controversy would be the actual amount originally charged to the beneficiary for the items or services in the disputed claim, as we stated in the proposed rule we believed that the amount originally charged to the beneficiary is more reflective of the actual amount at issue for the beneficiary and for the provider or supplier in this situation. We also stated we believed appellants would have access to and would use the same information for determining the basis for the amount in controversy under paragraph § 405.1006(d)(2)(iii) as they would under § 405.1006(d)(2)(ii).

As discussed above, we proposed at § 405.1006(d)(3) through (7) five exceptions to the general methodology used to calculate the amount in controversy specified in § 405.1006(d)(1). Current § 405.1006(d)(2) provides that, notwithstanding current § 405.1006(d)(1), when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 or if that liability was not limited under § 411.402, reduced by any deductible and coinsurance amounts applicable in the particular case. We proposed to re-designate current § 405.1006(d)(2) as § 405.1006(d)(3) and to revise the paragraph to state that when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy would be calculated in accordance with § 405.1006(d)(1) and (2)(i), except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under § 411.400 or as a result of liability that is limited under § 411.402. For example, when a claim for items or services is denied under section 1862(a)(1)(A) of the Act because the items or services were not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, Medicare payment may nonetheless be made under the limitation on liability provisions of section 1879 of the Act if neither the provider/supplier nor the beneficiary knew, or could reasonably have been expected to know, that payment would not be made. In instances such as these,

we proposed that the amount in controversy would be calculated as if the items or services in the disputed claim were denied and no payment had been made under section 1879 of the Act. We stated in the proposed rule that we believed this exception was appropriate because appellants may still wish to appeal findings of non-coverage related to items and services for which liability of the party was limited or payment was made under section 1879 of the Act or § 411.400 or for which the beneficiary was indemnified under § 411.402, but if these payments or indemnifications were deducted from the basis for the amount in controversy, the amount in controversy could be zero. As this exception relates only to whether deductions are made under § 405.1006(d)(1)(i) for any Medicare payments already made or awarded for the items or services, and the amount in controversy would otherwise be calculated in accordance with proposed § 405.1006(d)(1) and (d)(2)(i), we stated we believed appellants would have access to and would use the same information for determining the amount in controversy under § 405.1006(d)(3) as they would under § 405.1006(d)(1) and (d)(2)(i).

Current § 405.1006 does not address calculating the amount in controversy for matters involving a provider or supplier termination of a Medicare-covered item or service when the beneficiary did not elect to continue receiving the item or service (for example, § 405.1206(g)(2) provides that if a beneficiary is dissatisfied with a QIO's determination on his or her discharge and is no longer an inpatient in a hospital, the determination is subject to the general claims appeal process). In this circumstance, items and services have not been furnished, and therefore, a claim has not been submitted. Yet the beneficiary may elect not to continue receiving items or services while appealing the provider or supplier termination due to potential financial responsibility for the items or services. While an amount in controversy cannot be assessed for a period of time during which no items or services were furnished, a beneficiary may assert a continuing need for the items or services based on his or her condition at the time an appeal is heard. To address this circumstance, we proposed new § 405.1006(d)(4), which would provide that when a matter involves a provider or supplier termination of Medicare-covered items or services and the beneficiary did not elect to continue receiving the items or services that are disputed by a

beneficiary, the amount in controversy is calculated as discussed above regarding proposed (d)(1) and (d)(2)(ii) (which addresses situations where the beneficiary is determined to be financially responsible), except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services that the beneficiary asserts should be covered by Medicare based on the beneficiary's current condition at the time an appeal is heard, and Medicare payment was not made. We stated that this proposal would allow the beneficiary to pursue coverage for an item or service and potentially meet the amount in controversy requirement in instances in which he or she would not otherwise be able to pursue a hearing before an ALJ because no items or services have been rendered and therefore no amount in controversy exists because there is no disputed claim. In these instances, the beneficiary has been notified of a preliminary decision by a provider or supplier that Medicare will not cover continued provision of the items or services in dispute. Therefore, we stated in the proposed rule that we believed using the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services that the beneficiary asserts should be covered and if Medicare payment were not made for these items or services (in other words, the amount the beneficiary would be charged if the beneficiary were financially responsible for these items or services) is most reflective of the actual amount in dispute. Most beneficiary appeals of provider or supplier terminations of Medicare-covered items or services involve the termination of Part A services and, therefore, we stated that we expected it would be rare that the amount in controversy would be less than that required for an ALJ hearing. However, we also stated that we expected that beneficiaries wishing to determine if the amount in controversy required for an ALJ hearing was met could obtain from the provider or supplier the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services and Medicare payment were not made. In addition, as discussed below, we proposed at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ

hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We considered using Medicare payable amounts for denied items and services as the basis for the amount in controversy calculation specified in proposed § 405.1006(d)(1), as we stated that would be a more precise estimate of the amount at issue in the appeal than either the Medicare allowable amount or the billed charges. Payable amounts would take into account payment rules related to the items and services furnished that may increase or decrease allowable amounts (for example, multiple surgery reductions, incentive payments, and competitive bidding payments). However, we stated that CMS systems do not currently calculate payable amounts for denied services, and undertaking major system changes would delay implementation and has been determined not to be cost effective. While payable amounts may be a better representation of the amount at issue in the appeal, we stated in the proposed rule that we believed the Medicare allowable amount and the other amount in controversy calculations provided in proposed § 405.1006(d) are appropriate and reliable estimates that align well with the amount at issue for claims for which a payable amount has not been calculated.

However, we stated that for post-payment denials, or overpayments, a payable amount has been determined and would be the most reliable indicator of the amount actually at issue in the appeal. Therefore, we proposed new § 405.1006(d)(5) to state that, notwithstanding the calculation methodology in proposed paragraphs (d)(1) and (2), when a claim appeal involves an overpayment determination, the amount in controversy would be the amount of the overpayment specified in the demand letter. In a post-payment denial, the amount of the overpayment identified in the demand letter is readily available to appellants, and is the most accurate reflection of the amount actually at issue in the appeal. In addition, current § 405.1006 does not address appeals that involve an estimated overpayment amount determined through the use of sampling and extrapolation. In this circumstance, the claims sampled to determine the estimated overpayment may not individually meet the amount in controversy requirement, but the estimated overpayment determined

through the use of extrapolation may meet the amount in controversy requirement. To address this circumstance, we also proposed in new § 405.1006(d)(5) that when a matter involves an estimated overpayment amount determined through the use of sampling and extrapolation, the estimated overpayment as extrapolated to the entire statistical sampling universe is the amount in controversy. We stated that this proposal would provide appellants the opportunity to appeal claims that may not individually meet the amount in controversy requirement if such claims were part of the sample used in making an overpayment determination that does meet the amount in controversy requirement. Because the overpayment determination reflects the amount for which the appellant is financially responsible, we stated in the proposed rule that we believed it would be appropriate to allow appellants to appeal individual claims in the sample that was used to determine the overpayment. Whether an appeal involves an individual overpayment or an estimated overpayment determined through the use of sampling and extrapolation, we stated in the proposed rule that we believed appellants against whom an overpayment was assessed would need only to consult the demand letter they received in order to determine the amount in controversy. However, we also stated that we expected there may be circumstances where a beneficiary wishes to appeal an overpayment that was assessed against a provider or supplier, and in these situations the beneficiary may not have a copy of the demand letter that was received by the provider or supplier. For this reason, and as discussed below, we proposed at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We also proposed new § 405.1006(d)(6), which would provide that when a beneficiary files an appeal challenging only the computation of a coinsurance amount, or the amount of a remaining deductible applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as



determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct. We stated in the proposed rule that we believed this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for a paid claim. In addition, we also stated that we believed that the calculation proposed at § 405.1006(d)(6) would appropriately reflect the amount at issue for the beneficiary in these appeals where the computation of a coinsurance amount, or the amount of a remaining applicable deductible is challenged. We further stated that we believed beneficiaries would have access to the coinsurance and/or deductible amounts determined by the contractor for the paid claim on the beneficiary's Medicare Summary Notice, in the column titled "Maximum You May Be Billed," and would need only to subtract the amount of coinsurance and/or deductible the beneficiary believes he or she should have been charged in order to arrive at the amount in controversy. We stated we expected it would be extremely rare for a non-beneficiary appellant to file an appeal challenging the computation of a coinsurance amount or the amount of a remaining deductible.

In addition, we proposed new § 405.1006(d)(7) to provide that for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected in the published Medicare fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services. We stated in the proposed rule that we believed this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for such paid claims. In addition, we stated we believed that the calculation proposed at § 405.1006(d)(7) would appropriately reflect the amount at issue for the appellant in these appeals. We also stated that we believed that, generally, these types of appeals are filed by

providers and suppliers who are already familiar with the allowable amount for the items or services in the disputed claim based on information obtained from published fee schedules or contractor-priced amounts. Further, we stated that we believed that a fee schedule or contractor price challenge filed by a beneficiary on a paid claim would be a very rare occurrence. However, as discussed below, in the event a beneficiary would want to file such an appeal, the beneficiary could obtain an estimate of the amount in controversy from the QIC reconsideration. As discussed further below, we proposed at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

In the event that a reconsideration, or a redetermination if the appeal was escalated from the QIC without a reconsideration, involves multiple claims and some or all do not meet the amount in controversy requirement, section 1869 of the Act states that, in determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve the delivery of similar or related services to the same individual by one or more providers or suppliers, or common issues of law and fact arising from services furnished to two or more individuals by one or more providers or suppliers. Under this authority, § 405.1006(e) provides for aggregating claims to meet the amount in controversy requirement.

The title of current § 405.1006(e)(1) for aggregating claims when appealing a QIC reconsideration is phrased differently than the corresponding title for aggregating claims when escalating a request for a QIC reconsideration in current § 405.1006(e)(2), which may cause confusion. We proposed to revise the title to § 405.1006(e)(1) to "Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing" so it clearly applies to aggregating claims in appeals of QIC reconsiderations, and is parallel to the phrasing used in the title of § 405.1006(e)(2). The proposed titles of § 405.1006(e)(1) and (e)(2), and proposed § 405.1006(e)(2)(ii) would also replace "to the ALJ level" with "for an ALJ hearing" to again highlight that the appeal of a QIC reconsideration or

escalation of a request for a QIC reconsideration is for an ALJ hearing.

Current § 405.1006(e)(1)(ii) provides that to aggregate claims, the request for ALJ hearing must list all of the claims to be aggregated. We stated in the proposed rule that this has caused confusion because some appellants read current § 405.1006(e)(1)(ii) as allowing appeals of new claims to be aggregated with claims in previously filed appeals, provided the new request for hearing lists the claims involved in the previously filed appeals. However, current § 405.1006(e)(2)(i), which applies to aggregating claims that are escalated from the QIC for a hearing before an ALJ, requires that the claims were pending before the QIC in conjunction with the same request for reconsideration. We noted in the proposed rule that in the context of a request for hearing, aggregating new claims with claims from previously filed requests could delay the adjudication of the requests and is inconsistent with the current rule for aggregating claims that are escalated from the QIC. To address these issues and bring consistency to the aggregation provisions, we proposed to revise § 405.1006(e)(1)(ii) to require the appellant(s) to request aggregation of the claims in the same request for ALJ hearing or in multiple requests for an ALJ hearing filed with the same request for aggregation. We stated that this would allow an individual or multiple appellants to file either one request for an ALJ hearing for multiple claims to be aggregated, or multiple requests for an ALJ hearing for the appealed claims when requesting aggregation, while requiring them to be filed together with the associated request for aggregation. We also proposed in § 405.1006(e)(1)(iii) and (e)(2)(iii) that an ALJ or attorney adjudicator may determine that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, but only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. We proposed this because an attorney adjudicator adjudicating requests for an ALJ hearing when no hearing is conducted, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), would not be permitted under this proposed rule to dismiss a request for an ALJ hearing due to procedural issues such as an invalid aggregation

request. Because only an ALJ would be permitted to dismiss a request for an ALJ hearing because there is no right to a hearing, which includes not meeting the amount in controversy requirement for a hearing, in accordance with proposed § 405.1052(a), an attorney adjudicator could not make a determination that the aggregation criteria were not met because that determination would result in a dismissal of a request for an ALJ hearing.

Current § 405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. We proposed to revise § 405.976(b)(7) to require that the QIC notice of reconsideration include a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable. In line with current practice, we did not propose to require that the QIC indicate what it believes to be the exact amount in controversy, but rather only an estimate of whether it believes the amount in controversy is met, because, as we stated in the proposed rule, we believe the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator (though, as discussed in section II.B of the proposed rule and II.A.2 of this final rule above, only an ALJ would be able to dismiss a request for hearing for failure to meet the amount in controversy required for an ALJ hearing). We stated in the proposed rule that we believe that providers, suppliers, and Medicaid State agencies have the tools, resources, and payment information necessary to calculate the amount in controversy in accordance with § 405.1006(d), and are familiar with the allowable amounts for the places of service in which they operate. Furthermore, applicable plans against whom a Medicare Secondary Payer overpayment is assessed would have access to the overpayment amount specified in the demand letter, which would be used to determine the amount in controversy under proposed § 405.1006(d)(5). Thus, we stated that we did not believe it was necessary for the QICs to continue to provide this

statement for providers, suppliers, applicable plans, Medicaid State agencies, or beneficiaries represented by providers, suppliers or Medicaid State agencies. Furthermore, as discussed in section III.A.3.g.i of the proposed rule and II.B.3.g.i of this final rule below, we proposed that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, include the amount in controversy in their requests for hearing (unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). As providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency would be responsible for calculating the amount in controversy and including it on the request for hearing as proposed in section III.A.3.g.i of the proposed rule (and discussed in section II.B.3.g.i below), we stated that we did not believe a statement by the QIC that indicates only whether the amount in controversy was or was not met adds significant value to such appellants. Furthermore, we expected that the Medicare allowable amount under proposed § 405.1006(d)(2)(i)(A) would be the basis for the amount in controversy in the majority of Part B appeals filed by non-beneficiary appellants. While QICs have access to the amount charged to an individual based on billed charges, the allowable amounts for claims vary based on where these items and services were furnished, and the applicable fee schedules and contractor-priced amounts, and continuing to require the QICs to include a statement whether the amount in controversy needed for an ALJ hearing is met in all instances in which the decision is partially or fully unfavorable to the appellant would require substantially more work by the QIC, and could delay reconsiderations and increase costs to the government.

Although we did not propose that beneficiaries who are not represented by a provider, supplier, or Medicaid State agency would need to include the amount in controversy on their requests for hearing (as discussed later in this preamble), we stated in the proposed rule that we believed there may be instances where a beneficiary would want to know if the amount in controversy meets the amount required for an ALJ hearing when deciding whether to file a request for hearing. We also stated we believed there may be

instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not currently have sufficient information to determine whether the amount in controversy required for an ALJ hearing is met under proposed § 405.1006. For example, under proposed § 405.1006(d)(2)(i)(A), for items and services with a published Medicare fee schedule or published contractor-priced amount (and for which the beneficiary was determined to be not financially responsible), the basis for the amount in controversy would generally be the allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service. Beneficiaries not represented by a provider, supplier, or Medicaid State agency would not generally be expected to be familiar with fee schedule and contractor-priced amounts, and we stated we believed they may have difficulty determining whether the amount in controversy required for an ALJ hearing is met in these cases. We also stated we believed beneficiaries not represented by a provider, supplier, or Medicaid State agency might be unable to determine the amount of an overpayment assessed against a provider or supplier for items or services furnished to the beneficiary for purposes of calculating the amount in controversy under proposed § 405.1006(d)(5), as the beneficiary might not have access to the demand letter received by the provider or supplier, and may no longer have access to the Medicare Summary Notice reflecting the original payment amount. Accordingly, because there are situations where such beneficiaries may not have sufficient information to determine the amount in controversy, we proposed to revise § 405.976(b)(7) to state that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

Current § 423.1970 describes the amount in controversy requirement for part 423, subpart U proceedings. For the same reasons we proposed to revise § 405.1006(e)(1)(ii), we proposed in § 423.1970(c)(1)(ii) and (c)(2)(ii) to provide that a single enrollee's or multiple enrollees' request for

aggregation, respectively, must be filed at the same time the request (or requests) for hearing for the appealed reconsiderations is filed. In addition, we proposed to revise § 423.1970(c)(1)(ii) and § 423.1970(c)(2)(ii) to state that the request for aggregation and requests for hearing must be filed within 60 calendar days after receipt of the notice of reconsideration for each reconsideration being appealed, unless the deadline is extended in accordance with § 423.2014(d). Our proposal would help ensure there is no confusion that the timely filing requirement applies to each of the requests for hearing filed with the request for aggregation. Because we proposed to directly reference the 60 calendar day filing requirement under § 423.1972(b) and the possible extension of the filing requirement under § 423.2014(d), we also proposed to remove the current references in § 423.1970(c)(1)(ii) and (c)(2)(ii) to the filing requirement in § 423.1972(b). In addition, for the same reasons we proposed to revise § 405.1006(e)(1)(iii) and (e)(2)(iii), we proposed in § 423.1970(c)(1)(iii) and (c)(2)(iii) that an ALJ or attorney adjudicator may determine that the appeals that a single enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate involve the same prescription drugs, but only an ALJ may determine appeals that a single enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate do not involve the same prescription drugs. We proposed to replace “prescription” in current § 423.1970(c)(2)(iii) with “prescription drugs” in proposed § 423.1970(c)(2)(iii) for consistency with current and proposed § 423.1970(c)(1)(iii). Finally, we also proposed to correct the spelling of “prescription” in current § 423.1970(c)(2)(iii).

Current § 422.600(b) provides that the amount in controversy for appeals of reconsidered determinations to an ALJ (under the Part C MA program), is computed in accordance with part 405. However, if the basis for the appeal is the MAO’s refusal to provide services, current § 422.600(c) provides that the projected value of those services are used to compute the amount in controversy. We did not propose to revise these provisions because, as we stated in the proposed rule, we believed the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed

under part 422, subpart M. In particular, we noted that as is the case under current § 405.1006, if an enrollee received items or services and is financially responsible for payment because the MAO has refused to cover the item or services, the amount in controversy would be calculated using the billed charges as the basis for the amount in controversy, as provided in proposed § 405.1006(d)(2)(ii). We stated that if the enrollee did not receive the items or services, the provisions of current § 422.600(c) would apply. We also noted that current §§ 422.622(g)(2) and 422.626(g)(3) provide for an appeal to an ALJ, the Council, or federal court of an IRE’s affirmation of a termination of provider services “as provided for under [part 422, subpart M],” thus triggering the amount in controversy rules in 422.600, which cross-reference part 405 (that is, the rules proposed here). We stated that proposed § 405.1006 would address scenarios appealed under part 422, subpart M that are not clearly addressed in current § 405.1006, such as provider service terminations, which would be addressed in proposed § 405.1006(d)(4), and coinsurance and deductible challenges, which would be addressed in proposed § 405.1006(d)(6).

Current § 478.44(a) also references back to part 405 provisions for determining the amount in controversy when requesting an ALJ hearing after a QIO reconsidered determination. We proposed revisions to § 478.44 in section III.D.3 of the proposed rule (as discussed in section II.E.3 below), to update part 405 references, but we did not propose in § 478.44 to revise how the current or proposed part 405 provision would be applied in calculating the amount in controversy. Similar to the part 422, subpart M provisions discussed above, we stated that we believe the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed under part 478, subpart B.

We received 14 comments on these proposals. Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Two commenters supported our proposal to revise the title of § 405.1006 to reflect that the amount in controversy threshold is required “for an ALJ hearing and judicial review” rather than “to request an ALJ hearing and judicial review.” One commenter felt that this revision would more closely align the regulation with the corresponding statutory provision at § 1869(b)(1)(E) of the Act.

The other commenter believed that the current title of § 405.1006 may have resulted in beneficiaries not filing a request for hearing if they were confused or unsure about whether the minimum amount in controversy was met.

*Response:* We thank the commenters for their support, and we are finalizing the proposal to revise the title of § 405.1006 without modification.

*Comment:* Six commenters opposed our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, and recommended we withdraw the proposal or publish user-friendly, online resources to help the public better understand the proposed calculation methodology. In general, the commenters felt that the proposal would prevent physicians, beneficiaries, and other appellants from appealing low-dollar claims and, rather than streamlining the appeals process, the proposal would create confusion among appellants, ALJs, and attorney adjudicators. One commenter recommended that the higher of the Medicare allowable amount or the amount charged the individual for the items or services in question be used to determine the amount in controversy.

*Response:* As explained above, we proposed to revise the calculation methodology for the amount in controversy in order to arrive at an amount that more accurately reflects the amount at stake for appellants. We estimated in section VI (Regulatory Impact Statement) of the proposed rule (81 FR 43790, 43856) that our proposals could remove appeals related to over 2,600 low-value Part B claims per year from the ALJ hearing process, after accounting for the likelihood that appellants would aggregate claims to meet the minimum amount in controversy required for an ALJ hearing. However, we noted in the proposed rule that appeals filed by Medicare beneficiaries and MA and Part D prescription drug plan enrollees would be minimally impacted because these individuals often appeal claim or coverage denials for which they are financially responsible, and for which we would continue basing the amount in controversy on the provider or supplier’s billed charges.

After considering the comments received and further analysis of our proposal to revise the calculation of the amount in controversy to use the Medicare allowable amount as set forth in proposed § 405.1006(d)(2)(i)(A), we

have decided not to finalize proposed § 405.1006(d)(2)(i)(A) at this time. While we continue to believe that the amount in controversy should more closely reflect the actual amount at stake in an appeal, we believe that the costs to the appellant community and the government outweigh the benefits of fewer appeals entering the ALJ hearing process under the proposed methodology for calculating the amount in controversy.

Based on further analysis spawned by the public comments, we believe the costs of the proposal are likely higher than originally anticipated. These costs include costs to the appellant community in identifying the published Medicare fee schedule or published contractor-priced amount to include in the request for hearing; and the administrative costs to the government of calculating the amount for certain appellants, and verifying and resolving conflicts over the calculation. While our estimation of 2,600 fewer appeals for low-value claims that we believe would enter the appeals process if the proposal were finalized does provide a clear benefit, we estimate the costs to the Federal government would be roughly twice the projected benefit and recognize the appellant community would incur additional costs as well. Therefore, we do not believe this estimated benefit outweighs the potential costs at this time based on our revised analysis.

Thus, at this time we are not finalizing our proposal under § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we are not finalizing proposed § 405.1006(d)(2)(i)(B), because, given that we are not finalizing proposed § 405.1006(d)(2)(i)(A), there is no longer a need to distinguish between items and services with and without a published Medicare fee schedule or contractor-priced amount. Instead, we will continue to use the methodology specified in § 405.1006(d)(1) as the general methodology for calculating the amount in controversy, except that we are finalizing our proposal to replace “for the items and services in question” with “for the items and services in the disputed claim” in § 405.1006(d)(1) introductory text because the amount in controversy is calculated on a claim-by-claim basis, and there has been confusion when a single reconsideration decision involves multiple claims. We are also replacing “applicable in the particular case” with “that may be

collected for the items or services” in § 405.1006(d)(1)(ii) because, as explained above and in section III.A.3.d of the proposed rule, there may be situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible amounts, or must refund any such amounts already collected, and in these situations the amount in controversy should not be reduced by that amount. Furthermore, because we will continue to use § 405.1006(d)(1), as revised above, we are not finalizing proposed § 405.1006(d)(1).

In addition, we also are not finalizing proposed § 405.1006(d)(2)(ii) and (iii) because there is no need to define the basis for the amount in controversy in specific situations, as the amount in controversy would be calculated on the basis of the amount charged the individual in all of the scenarios described in proposed § 405.1006(d)(2)(i) through (iii). However, for the reasons discussed above and in section III.A.3.d of the proposed rule, we continue to believe that it would be appropriate to finalize separate calculations of the amount in controversy to address the situations in proposed § 405.1006(d)(3) through (7). Therefore, we are finalizing, with the modifications discussed below, the exceptions to the general calculation methodology that we proposed at § 405.1006(d)(3) through (7), which are being renumbered as § 405.1006(d)(2) through (6) in this final rule.

*Comment:* One commenter supported our proposal to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. Another commenter supported our proposal to continue using the provider’s or supplier’s billed charges as the basis for calculating the amount in controversy for appeals of claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (subject to the exceptions delineated in the proposed rule).

*Response:* We thank the commenters for their support. However, for the reasons explained above, we are not finalizing our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount.

*Comment:* One commenter stated that the proposed rule “establishes the minimum amounts in controversy for a

hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy.” The commenter also stated that the proposal to use the Medicare allowable amount as the basis for the amount in controversy for appeals of claims that are priced based on a published Medicare fee schedule or published contractor-priced amount, could be burdensome for MAOs, who would need to provide their contracted rates for every provider and plan type for appeals that involve supplemental benefits offered by the plan. Finally, the commenter requested clarification on how the proposal would affect pre-service requests for coverage.

*Response:* We disagree with the comment that the proposed rule would establish the minimum amounts in controversy for an ALJ hearing and judicial review, but that it would not establish how to calculate the amount in controversy. Section 1869(b)(1)(E) of the Act establishes the amount in controversy threshold amounts for an ALJ hearing and judicial review at \$100 and \$1,000, respectively, for Medicare Part A and Part B appeals, adjusted annually by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of \$10. Section 1869(b)(1)(E) of the Act is then referenced and the same amount in controversy thresholds and adjustments are made applicable to competitive medical plan (also known as cost plan) appeals in section 1876(c)(5)(b) of the Act, to Part C MA appeals in section 1852(g)(5) of the Act, and to Part D Prescription Drug appeals in section 1860D–4(h) of the Act (by reference back to section 1852(g) of the Act). Thus, the minimum amount in controversy thresholds required for an ALJ hearing and judicial review are established by statute, and are reflected in the regulations at current § 405.1006(b) and (c).

However, as we explained above and in the proposed rule, the statute does not specify how to calculate the amount in controversy. Section 405.1006(d)(1) provides that, subject to the exception in paragraph (d)(2), the amount in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by any Medicare payments already made or awarded for the items or services and any deductible or coinsurance amounts applicable in the particular case. Because the actual amount charged the individual may not

always be an accurate reflection of the amount at issue for appellants, we proposed to revise the calculation methodology in § 405.1006(d) in a manner that better aligns the amount in controversy with the amount at stake in an appeal. In general, we proposed in § 405.1006(d)(1) that, subject to certain exceptions, the amount in controversy would be the calculated as the basis for the amount in controversy as defined in paragraph (d)(2), reduced by any Medicare payments already made or awarded for the items or services and any deductible and/or coinsurance amounts that may be collected for the items or services. In proposed § 405.1006(d)(2), we explained how the basis for the amount in controversy would be calculated in different situations, and in § 405.1006(d)(3) through (7) we proposed five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

With regard to the commenter's concern that under our proposal at § 405.1006(d)(2)(i)(A), MAOs would need to provide their contracted rates for appeals that involve supplemental plan benefits, and the commenter's request for clarification regarding how this proposal would affect pre-service requests for coverage, we note that, for the reasons explained above, we are not finalizing our proposal in § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, nor are we finalizing proposed § 405.1006(d)(2)(ii) or (d)(2)(iii).

*Comment:* Two commenters suggested HHS consider increasing the minimum amount in controversy required for an ALJ hearing. One of these commenters recommended raising the minimum amount in controversy from \$100 to \$300, and the other recommended raising it from \$100 to \$500. (As the annually adjusted amount in controversy threshold for an ALJ hearing was \$150 at the time the comments were received, we presume the commenters are referring to the amount in controversy without regard to the annual adjustments required under section 1869(b)(1)(E)(iii) of the Act.) The commenters stated that raising the amount in controversy would reduce the number of appeals for small-dollar claims and generate savings in adjudication costs for the government and staffing costs for health plans.

*Response:* The amount in controversy threshold required for an ALJ hearing is specified in section 1869(b)(1)(E) of the

Act. We appreciate the commenters' recommendations, but we do not have the authority to change the amount in controversy threshold specified in the statute.

*Comment:* One commenter observed that claim determinations resulting from a single audit are frequently separated into multiple overpayment recovery actions, which increases administrative burden on appellants and CMS, and also may make it difficult for appellants to aggregate claims to meet the amount in controversy requirement because the overpayment recovery actions often occur on different dates. The commenter recommended the agency prohibit Medicare contractors from separating claims that result from the same audit or investigation. Another commenter felt our proposals at §§ 405.1006(e)(1)(iii), (e)(2)(iii), 423.1970(c)(1)(iii), and (c)(2)(iii) providing that only an ALJ could determine that a request for aggregation was invalid were overly complicated, could make the role of an attorney adjudicator duplicative, and, without appropriate safeguards, could result in an ALJ merely adopting an attorney adjudicator's recommendation on whether a request for aggregation was valid without further review.

*Response:* With regard to the recommendation that the agency prohibit contractors from separating claims that result from the same audit or investigation, we note that permitted practices for CMS contractor audits are not within the scope of this rulemaking. We do not agree with the commenter that our proposal that only an ALJ can determine the invalidity of a request for aggregation is overly complicated. As explained above and in section III.A.3.d of the proposed rule, we believe that only an ALJ can determine the invalidity of a request for aggregation, because that determination would result in a dismissal of a request for an ALJ hearing. However, we believe it would be unnecessary and inefficient to require an ALJ to determine that a request for aggregation was valid for an appeal that was assigned to an attorney adjudicator. With respect to the concern that the ALJ could merely adopt the attorney adjudicator's recommendation on whether a request for aggregation was valid without further review, we note that § 405.1006(e)(1) and (2), as finalized in this rule, provide that only an ALJ may determine that the claims were not properly aggregated and therefore do not meet the minimum amount in controversy required for an ALJ hearing. Thus, the ALJ is required to make this determination, and would not be permitted to simply adopt the

attorney adjudicator's preliminary determination without doing an independent review. We address the commenters concerns regarding the role of an attorney adjudicator compared to that of an ALJ more fully in section II.A.2 above.

*Comment:* One commenter stated that, for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) claims, in the case of an unrepresented beneficiary, the amount in controversy should include any set-up, handling or freight charges incurred in delivering the item to the beneficiary. The commenter stated that this amount is included in the allowable amount, but that the basis for the amount in controversy in situations described in proposed § 405.1006(d)(2)(iii) (where the beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority) would be the actual amount originally charged to the beneficiary for those items and services as delivered to the beneficiary.

*Response:* We believe the commenter is requesting to define the basis in proposed § 405.1006(d)(2)(iii) as the amount originally charged to the beneficiary for the items or services, including any set-up or delivery fees. Because we are not finalizing our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, as discussed above, we are not finalizing proposed § 405.1006(d)(2)(iii) to define the basis for the amount in controversy when a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority. Under proposed § 405.1006(d)(2)(iii), the basis for the amount in controversy would be the actual amount originally charged to the beneficiary. We proposed § 405.1006(d)(2)(iii) as an exception to the calculation in proposed § 405.1006(d)(2)(i) in situations where the beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier under applicable authority. Because we are no longer finalizing § 405.1006(d)(2)(i) as proposed, there is no longer a need to finalize § 405.1006(d)(2)(iii). Therefore, as discussed above, the amount in

controversy in this situation would be calculated as provided under § 405.1006(d)(1) as finalized in this rule (the actual amount charged the individual for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded and any deductible and/or coinsurance amounts that may be collected for the items or services). In most cases, we expect that the amount charged the individual for the items and services in the disputed claim would be inclusive of delivery and set-up expenses. Subject to a few exceptions, suppliers rarely include a separate charge for delivery and set-up. Delivery and service are an integral part of a DME supplier's cost of doing business, and such costs are ordinarily assumed to have been taken into account by suppliers in setting the prices they charge for covered items and services (see Medicare Claims Processing Manual (Internet-Only Manual 100-04), chapter 20, section 60). As such, and as noted by the commenter, these costs have already been accounted for in the calculation of the fee schedules, and separate delivery and service charges for DME items are not permitted except in rare and unusual circumstances. In the rare and unusual circumstances where a separate charge is permitted (for example, when a supplier delivers an item outside the area in which the supplier normally does business), that charge, if billed on the same claim, would be factored into the amount charged the individual for purposes of calculating the amount in controversy under § 405.1006(d)(1) as finalized in this rule.

*Comment:* One commenter opposed our revision to current § 405.1006(d)(2), which we proposed to re-designate as § 405.1006(d)(3), because the commenter felt that current § 405.1006(d)(2) was easier to understand.

*Response:* Because we are not finalizing our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, we are also not finalizing our proposal to revise and re-designate current § 405.1006(d)(2), except the proposal to add "Limitation on liability" as a paragraph heading. In addition, for consistency with paragraph (d)(1)(ii) as finalized in this rule, we are also replacing the phrase "any deductible and coinsurance amounts applicable in the particular case" as set forth in current § 405.1006(d)(2) with "any

deductible and/or coinsurance amounts that may be collected for the items or services."

*Comment:* One commenter asked how to calculate the amount in controversy when Medicare is secondary to another insurer and makes a supplemental payment under § 411.32 because the primary payment is less than the charges for the services, but the supplemental payment amount is less than required under § 411.33(a) or (e). The commenter also asked why in these instances the beneficiary's Medicare Summary Notice (MSN) does not include a footnote stating that the amount of Medicare's payment was determined in accordance with § 411.33(a) or (e).

*Response:* Under current § 405.1006(d), the amount in controversy in this situation is calculated as the amount charged the individual for the items and services in question, reduced by any Medicare payments already made or awarded for the items or services and any deductible and coinsurance amounts applicable in the particular case, regardless of any payment amounts made or awarded by the primary insurer. Because the scenario raised by the commenter does not fall under any of the exceptions in § 405.1006(d)(2) through (6) as finalized in this rule, the amount in controversy would continue to be calculated as provided under § 405.1006(d)(1) as finalized in this rule (the amount charged the individual for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services and any deductible and/or coinsurance amounts that may be collected for the items or services). The commenter's question regarding footnotes on Medicare Summary Notices is outside the scope of this rulemaking.

*Comment:* One commenter supported the addition of proposed § 405.1006(d)(4) to address how the amount in controversy is calculated for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. The commenter, a beneficiary advocacy organization, also asked what relief could be sought when a provider refuses to furnish or reinstate the terminated item or service after an ALJ determines the termination was not appropriate, or when the ALJ lacks the authority to rule on whether Medicare payment should be made for items or services that the beneficiary continued to receive (and paid for) after the termination date. The commenter was concerned that

beneficiaries receive inadequate notice of the limited scope of an ALJ's authority in these matters, and earlier notice on the scope of expedited appeals under part 405, subpart J and the right to request a demand bill could help avoid these situations.

*Response:* We thank the commenter for its support of our proposal to address how the amount in controversy is calculated for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. The comments regarding what relief may be sought when a provider refuses to furnish the terminated item or service after the ALJ determines the termination was not appropriate or when the ALJ lacks authority to rule on whether payment should be made for items or services that the beneficiary continued to receive after termination, and the suggestions regarding notice on the scope of expedited appeals and the right to request a demand bill are all outside the scope of this rulemaking. However, we may take them into consideration when making any future revisions to the provider service termination process.

*Comment:* We received two comments in support of our proposal at § 405.976(b)(7) to require QICs to include in their notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

*Response:* We thank the commenters for their support. As discussed in section II.B.3.d below, we are not finalizing our proposal under § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. However, we continue to believe that the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator. Therefore we are finalizing without modification our proposal to require QICs to include in their notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only

if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable. As we stated above and in section III.A.3.d of the proposed rule, we believe providers, suppliers, Medicaid State agencies, and applicable plans have the tools, resources, and payment information necessary to calculate the amount in controversy, and we believe that to be especially true in light of our decision not to finalize proposed § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. However, we recognize that beneficiaries may not have access to these same tools, resources, and payment information, and we believe it is appropriate for the QIC to continue furnishing an estimate of whether the amount in controversy is met for reconsiderations that are partially or fully unfavorable on requests for reconsideration filed by beneficiaries who are not represented by a provider, supplier, or Medicaid State agency.

*Comment:* We received several comments on our proposal under § 405.1014(a)(1)(viii) to require that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, to include the amount in controversy in their requests for hearing.

*Response:* We address these comments in sections II.B.3.g.i below.

After review and consideration of the comments received, for the reasons discussed above, we are finalizing proposed § 405.1006 with the following modifications. We are not finalizing our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we are not finalizing § 405.1006(d)(2)(i)(B), because, given that we are not finalizing § 405.1006(d)(2)(i)(A), there is no longer a need to distinguish between items and services with and without a published Medicare fee schedule or contractor-priced amount. We also are not finalizing proposed § 405.1006(d)(2) or (d)(2)(i) introductory text, as there is no need for this language given that we are not finalizing § 405.1006(d)(2)(i)(A) or (B). Accordingly, we are maintaining the text of current § 405.1006(d)(1), except that we are: (1) Adding “In general” as a paragraph heading as proposed; (2)

replacing “for the items and services in question” with “for the items and services in the disputed claim” in § 405.1006(d)(1) introductory text as proposed; and (3) replacing “Any deductible and coinsurance amounts applicable in the particular case” in current § 405.1006(d)(1)(ii) with “Any deductible and/or coinsurance amounts that may be collected for the items or services” as proposed. Furthermore, as discussed above, because we will continue to use current § 405.1006(d)(1) as revised above to calculate the amount in controversy, we are not finalizing proposed § 405.1006(d)(1) introductory text.

In addition, we also are not finalizing proposed § 405.1006(d)(2)(ii) and (iii) because there is no need to define the basis for the amount in controversy in specific situations, as the amount in controversy would be calculated on the basis of the amount charged the individual in all of the scenarios described in proposed § 405.1006(d)(2)(i) through (iii). Furthermore, we are not finalizing our proposal to revise and re-designate current § 405.1006(d)(2) as § 405.1006(d)(3), except for the proposal to add “Limitation on liability” as a paragraph heading. However, for consistency with paragraph (d)(1)(ii) as finalized, we are replacing “any deductible and coinsurance amounts applicable in the particular case” in current § 405.1006(d)(2) with “any deductible and/or coinsurance amounts that may be collected for the items or services.”

We are finalizing proposed § 405.1006(d)(4), (5), (6), and (7) with the modifications discussed below, but re-designating them as paragraphs (d)(3), (4), (5), and (6), respectively, because we are not finalizing proposed § 405.1006(d)(2) or re-designating current § 405.1006(d)(2) as § 405.1006(d)(3). We are replacing “in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy” in paragraph (d)(3) as finalized (proposed paragraph (d)(4)) with “in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual.” In addition, we are replacing “Notwithstanding paragraphs (d)(1) and (2) of this section” in paragraphs (d)(4), (5), and (6) as finalized (proposed paragraphs (d)(5), (6), and (7)) with “Notwithstanding paragraph (d)(1) of this section.”

Finally, we are finalizing our proposal to revise § 405.976(b)(7), the section heading of § 405.1006, and the changes to § 405.1006(e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory

text, (e)(2)(ii) and (iii), and § 423.1970(c)(1)(ii) and (iii), (c)(2)(ii) and (iii) as proposed, without modification.

e. Parties to an ALJ Hearing (§§ 405.1008 and 423.2008)

Current §§ 405.1008 and 423.2008 discuss the parties to an ALJ hearing. Because current §§ 405.1002(a) and 423.2002(a) already address who may request a hearing before an ALJ after a QIC or IRE issues a reconsideration and current § 405.1002(b) addresses who may request escalation of a request for a QIC reconsideration, we proposed to remove current §§ 405.1008(a) and 423.2008(a). 81 FR 43790, 43810.

We proposed to retain and revise the language as discussed below in current §§ 405.1008(b) and 423.2008(b), but remove the paragraph designation. Current §§ 405.1008(b) and 423.2008(b) identify the parties “to the ALJ hearing,” but this could be read to be limited to parties to an oral hearing, if a hearing is conducted. To address this potential confusion, we proposed to revise §§ 405.1008 and 423.2008 to replace “parties to an ALJ hearing” with “parties to the proceedings on a request for an ALJ hearing” and “party to the ALJ hearing” with “party to the proceedings on a request for an ALJ hearing.” Likewise, we also proposed to revise the titles to §§ 405.1008 and 423.2008 from “Parties to an ALJ hearing” to “Parties to the proceedings on a request for an ALJ hearing.” 81 FR 43790, 43810.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received one comment on proposed §§ 405.1008 and 423.2008 regarding parties to an ALJ hearing. The comment was submitted by a Recovery Auditor trade/advocacy group and expressed concerns about how the proposals related to status at ALJ hearings would impact CMS audit contractors’ interests in the hearings and their ability to elect party status.

*Response:* As we explain above, these proposals removed some redundancies in current §§ 405.1008(a) and 423.2008(a) and clarified the language to address potential confusion that the sections applied only to parties to an oral hearing, if a hearing is conducted, rather than to parties to the proceedings on a request for an ALJ hearing. Although the commenter included the caption to this proposal in its submission, the comments relate to proposed §§ 405.1010, 405.1012 and 423.2010. Therefore, we respond to this comment in section II.B.3.f.i below.



After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 405.1008 and 423.2008 as proposed without modification.

f. CMS and CMS Contractors as Participants or Parties in the Adjudication Process (§§ 405.1010, 405.1012, and 423.2010)

As further described below, we proposed significant revisions to §§ 405.1010 and 405.1012 regarding CMS and CMS contractors as participants or parties in proceedings on a request for an ALJ hearing, and to § 423.2010 regarding CMS, the IRE, or a Part D plan sponsor as participants in proceedings on a request for an ALJ hearing. 81 FR 43790, 43810–43816, 43862–43863, and 43879–43880.

i. Section 405.1010: When CMS or Its Contractors May Participate in the Proceedings on a Request for an ALJ Hearing

Current § 405.1010(a) provides that an ALJ may request, but may not require, CMS and/or its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any, and CMS or its contractors may elect to participate in the hearing process. Under current § 405.1010(b), if that election is made, CMS or its contractor must advise the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 calendar days after receiving the notice of hearing. Section 405.1010(c) sets forth what participation includes and § 405.1010(d) states that participation does not include CMS or its contractor being called as a witness during the hearing. Section 405.1010(e) requires CMS or its contractors to submit any position papers within the time frame designated by the ALJ. Finally, § 405.1010(f) states that the ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

We stated in the proposed rule that the reference to the period in which an election to participate must be filed beginning upon receipt of the notice of hearing in current § 405.1010(b) has caused confusion when CMS or its contractors attempt to enter proceedings before a hearing is scheduled, or when no notice of hearing is necessary because an appeal may be decided on the record. To help ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process

prior to a hearing being scheduled or when a hearing may not be conducted, we proposed in § 405.1010(a)(1) to provide that CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b), at either of, but not later than, two distinct points in the adjudication process described in paragraph (b)(3).

As provided in current § 405.1010(a) and (f), we proposed at § 405.1010(a)(2) that an ALJ may request but may not require CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any; and the ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings.

We proposed in § 405.1010(b) to address how CMS or a contractor makes an election to participate in an appeal, before or after receipt of a notice of hearing or when a notice of hearing is not required. Under § 405.1010(b)(1), we proposed that if CMS or a contractor elects to participate before receipt of a notice of hearing (such as during the 30 calendar day period after being notified that a request for hearing was filed as proposed in § 405.1010(b)(3)(i)) or when a notice of hearing is not required, CMS or the contractor must send written notice of its intent to participate to the parties who were sent a copy of the notice of reconsideration, and to the assigned ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), or if the appeal is not yet assigned, to a designee of the Chief ALJ. We proposed at § 405.1010(b)(1) to provide for sending the written notice of intent to participate to an ALJ or attorney adjudicator assigned to an appeal because, as we discussed in section II.B of the proposed rule and II.A.2 of this final rule above, an attorney adjudicator also would have the authority to issue decisions on a request for an ALJ hearing when no hearing is conducted, and in accordance with proposed § 405.1010, CMS or its contractors are permitted to participate in the proceedings on such a request. We also proposed at § 405.1010(b)(1) to provide for sending the notice of intent to participate to a designee of the Chief ALJ if a request for an ALJ hearing is not yet assigned to an ALJ or attorney adjudicator because CMS or a contractor could file an election to be a participant in the proceedings before the assignment process is complete. We stated in the proposed rule that proposed § 405.1010(b)(1) would help ensure that the potential parties to a

hearing, if a hearing is conducted, would receive notice of the intent to participate, and also help ensure that adjudicators who are assigned to an appeal after an election is made would be aware of the election. Because only an ALJ may conduct a hearing and the parties to whom a notice of hearing is sent may differ from the parties who were sent a copy on the notice of reconsideration, we proposed at § 405.1010(b)(2) that if CMS or a contractor elects to participate after receiving a notice of hearing, CMS or the contractor would send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

We proposed at § 405.1010(b)(3)(i) that CMS or a contractor would have an initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed with OMHA, if no hearing is scheduled. CMS and its contractors have the capability to see that a QIC reconsideration had been appealed to OMHA in the case management system used by QICs. This system would provide constructive notice to the QICs when the system indicates an appeal has been filed with OMHA, which OMHA can monitor through the date that the reconsideration data is transferred to OMHA to adjudicate the request for an ALJ hearing. Under proposed § 405.1010(b)(3)(ii), a second opportunity to elect to be a participant in an appeal would become available if a hearing is scheduled; as in the current rule, CMS or a contractor would have 10 calendar days after receiving the notice of hearing to make the election.

As we stated in the proposed rule, we considered allowing CMS or a contractor to make an election at any time prior to a decision being issued if a hearing was not scheduled, or sending a notice that a decision would be issued without a hearing and establishing an election period after such notice. However, both of these options would disrupt and delay the adjudication process, as well as add administrative burdens on OMHA. We stated in the proposed rule that we believed the 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS or a contractor to determine whether to elect to be a participant in the appeal while the record is reviewed for case development and to prepare for the hearing, or determine whether a decision may be appropriate based on the record in accordance with § 405.1038.

We proposed to consolidate current § 405.1010(c) through (e) in proposed

§ 405.1010(c) to address the roles and responsibilities of CMS or a contractor as a participant. Proposed § 405.1010(c)(1) would incorporate current § 405.1010(c), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we proposed to revise § 405.1010(c) to state in § 405.1010(c)(1) that participation may include filing position papers "and/or" providing testimony to emphasize that either or both may be done, and to state that participation would be subject to proposed § 405.1010(d)(1) through (3) (discussed below). We proposed to incorporate current § 405.1010(d) in proposed § 405.1010(c)(2) to provide that when CMS or a contractor participates in a hearing, they may not be called as witnesses and, thus, are not subject to examination or cross-examination by parties to the hearing. However, to be clear about how a party and the ALJ may address statements made by CMS or a contractor during the hearing given that limitation, we also proposed in § 405.1010(c)(2) that the parties may provide testimony to rebut factual or policy statements made by the participant, and the ALJ may question the participant about the testimony.

We proposed to incorporate current § 405.1010(e) in proposed § 405.1010(c)(3) with certain revisions as discussed below. Current § 405.1010(e) states that CMS or its contractor must submit any position papers within the time frame designated by the ALJ. We proposed in § 405.1010(c)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed § 405.1010(b), and require that copies of position papers and written testimony be sent to the parties. Specifically, we proposed in § 405.1010(c)(3)(i) that CMS or a contractor position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the scheduled hearing unless additional time is granted by the ALJ. We proposed to add "written testimony" to recognize that CMS or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We proposed to require position papers and written testimony be submitted within 14 calendar days after an

election if no hearing is scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also proposed to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time) to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Additionally, under proposed § 405.1010(c)(3)(ii), CMS or a contractor would need to send a copy of any position paper or written testimony submitted to OMHA to the parties who were sent a copy of the notice of reconsideration if the position paper or written testimony is submitted to OMHA before receipt of a notice of hearing, or to the parties who were sent a copy of the notice of hearing if the position paper or written testimony is submitted after receipt of a notice of hearing. Current § 405.1010 does not address the repercussions of a position paper not being submitted in accordance with the section. Therefore, we proposed in § 405.1010(c)(3)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper or written testimony to the parties, or fails to submit its position paper or written testimony within the established time frames. We stated in the proposed rule that this would help ensure CMS or contractor position papers and written testimony are submitted timely and shared with the parties.

Current §§ 405.1010 does not limit the number of entities that may elect to be participants, which currently includes participating in a hearing if a hearing is conducted, and current § 405.1012 does not limit the number of entities that may elect to be a party to a hearing. We stated in the proposed rule that this has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we proposed at § 405.1010(d)(1) that when CMS or a contractor has been made a party to the hearing under § 405.1012, CMS or a contractor that elected to be a participant under § 405.1010 may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case (oral testimony and attendance at the hearing would not be permitted). Similarly, we proposed at § 405.1010(d)(1) that CMS or a

contractor that elected to be a party to the hearing, but was made a participant under § 405.1012(d)(1), as discussed below, would also be precluded from participating in the oral hearing, but would be permitted to file a position paper and/or oral testimony to clarify factual or policy issues in the case. We proposed at § 405.1010(d)(2) that if CMS or a contractor did not elect to be a party to the hearing under § 405.1012, but more than one entity elected to be a participant under § 405.1010, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing, but additional entities that filed a subsequent response to the notice of hearing could file a position paper and/or written testimony to clarify factual or policy issues in the case (though they would not be permitted to attend the hearing or provide oral testimony). We proposed that the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the hearing for administrative efficiency. Under this approach, if multiple entities elected to participate in the proceedings prior to the issuance of a notice of hearing, in accordance with proposed § 405.1010(b)(1), any of these entities wishing to participate in the oral hearing would need to indicate this intention in the response to the notice of hearing. If more than one entity indicated its intention to attend and participate in the oral hearing, only the first entity to file its response would be permitted to do so. The remaining entities would be permitted only to file a position paper and/or written testimony (unless the ALJ grants leave to additional entities to attend the hearing, as discussed below). We considered an alternate proposal of the first entity that made an election to participate being given priority for participating in the hearing, but believed that would result in other participants being uncertain whether they will be participating in the hearing until as few as 5 days prior to the hearing. We also considered a process in which the ALJ would assess which participant that responded to the notice of hearing would be most helpful to the ALJ at the hearing, or in the alternative, permitting all participants to be at the hearing unless the ALJ determined a participant is not necessary for the hearing, but we were concerned that both of these approaches would add administrative burden to the ALJ and could result in participants and parties being uncertain of which participants will be at the hearing until shortly

before the hearing. We solicited comments on the alternatives considered above, and other potential alternatives.

Notwithstanding the limitations on CMS and CMS contractor participation in proposed § 405.1010(d)(1) and (2), we proposed in § 405.1010(d)(3) that the ALJ would have the necessary discretion to allow additional participation in the oral hearing when the ALJ determines an entity's participation is necessary for a full examination of the matters at issue. For example, we stated in the proposed rule that if an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. Similarly, if an overpayment determined through the use of a statistical sample and extrapolation is at issue, the ALJ may determine that allowing the contractor that conducted the sampling to participate in the hearing is necessary to address issues related to the sampling and extrapolation, in addition to another contractor that made an election to clarify the policy and factual issues related to the merits of claims in the sample.

Currently, there are no provisions in § 405.1010 to address the possibility of CMS or a contractor making an invalid election. We proposed to revise § 405.1010(e) to add new provisions to establish criteria for when an election may be deemed invalid and provide standards for notifying the entity and the parties when an election is deemed invalid. We proposed in § 405.1010(e)(1) that an ALJ or attorney adjudicator may determine an election is invalid if the election was not timely filed or the election was not sent to the correct parties. We stated that this would help ensure that CMS and its contractors make timely elections and inform parties of elections. To provide notice to the entity and the parties that an election was deemed invalid, we proposed in § 405.1010(e)(2) to require a written notice of an invalid election be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election. We proposed in § 405.1010(e)(2)(i) that if no hearing is scheduled for the appeal or the election was submitted after the hearing occurred, the notice of an invalid election would be sent no later than the date the decision, dismissal, or remand notice is mailed. We proposed in § 405.1010(e)(2)(ii) that if a hearing is scheduled for the appeal, the written notice of an invalid election would be sent prior to the hearing, and that if the

notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided.

ii. Section 423.2010: When CMS, the IRE, or Part D Plan Sponsors May Participate in the Proceedings on a Request for an ALJ Hearing

Current § 423.2010 is similar to current § 405.1010, except that CMS, the IRE, or the Part D plan sponsor may only request to participate, and the time periods to request to participate are shorter than the time periods to elect to participate under § 405.1010, which provides the ALJ with time to consider the request to participate and make a determination on whether to allow participation by the entity. In addition, current § 423.2010 addresses participation in Part D expedited appeals. Like proposed § 405.1010(a), we proposed at § 423.2010(a) to provide CMS, the IRE, and the Part D plan sponsor with an opportunity to participate in the proceedings on a request for an ALJ hearing at two distinct points in the adjudication process, but the current policy of requiring the entity to request to participate is maintained. We proposed at § 423.2010(b)(3)(i) and (ii) that, if no hearing is scheduled, CMS, the IRE and/or the Part D plan sponsor would have an initial opportunity to request to be a participant in an appeal within 30 calendar days after notification that a standard request for hearing was filed with OMHA, or within 2 calendar days after notification that a request for an expedited hearing was filed. We stated in the proposed rule that the initial 30 calendar day period after notification that a standard request for hearing was filed with OMHA would be the same time frame provided under § 405.1010 for initial CMS and contractor elections, and we stated that we believed that the 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS, the IRE, and the Part D plan sponsor to determine whether to request to be a participant in the proceedings and for the request to be considered and granted or denied as the case is reviewed to determine whether a decision may be appropriate based on the record in accordance with § 423.2038. We also stated we believed the 2 calendar day period after notification that an expedited request for hearing was filed is a reasonable period of time for CMS, the IRE, or the Part D plan sponsor to determine whether to request to be a participant in the proceedings given the 10-day

adjudication time frame. We proposed at § 423.2010(b)(3)(iii) and (iv) to provide a second opportunity to request to be a participant in an appeal if a hearing is scheduled. We proposed at § 423.2010(b)(3)(iii) that if a non-expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 5 calendar days after receiving the notice of hearing to make the request. We proposed at § 423.2010(b)(3)(iv) that if an expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 1 calendar day after receiving the notice of hearing to make the request. These time frames were carried over from current § 423.2010(b)(1) and (b)(3), and provide the ALJ with time to consider the request and notify the entity of his or her decision on the request to participate. As provided in current § 423.2010(a) and (g), we proposed at § 423.2010(a)(2) to provide that an ALJ may request but may not require CMS, the IRE, or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any, and that the ALJ may not draw any adverse inferences if CMS, the IRE, or the Part D plan sponsor declines to be a participant to the proceedings.

We proposed in § 423.2010(b) to adopt the standards governing how an election is made in proposed § 405.1010(b) in governing how a request to participate is made, except that an oral request to participate could be made for an expedited hearing, and OMHA would notify the enrollee of the request to participate in such cases.

Current § 423.2010(b)(2) and (b)(4) provide that an ALJ will notify an entity requesting to participate of the decision on the request within 5 calendar days for a request related to a non-expedited hearing, or 1 calendar day for a request related to an expedited hearing. We proposed to incorporate these time frames into proposed § 423.2010(c). In addition, we proposed in § 423.2010(c)(1) that if no hearing is scheduled, the notification is made at least 20 calendar days before the ALJ or attorney adjudicator (as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above)) issues a decision, dismissal, or remand. This would provide the participant with time to submit a position paper in accordance with proposed § 423.2010(d)(3)(i), as discussed below. We also proposed to incorporate current § 423.2010(c) into proposed § 423.2010(c), so that the provision clearly states that the assigned ALJ or attorney adjudicator (as proposed in section II.B of the proposed rule (and

discussed in section II.A.2 above)) has discretion to not allow CMS, the IRE, or the Part D plan sponsor to participate. We proposed in § 423.2010(c) that an attorney adjudicator as well as the ALJ may make a decision on a request to participate because a request to participate may be submitted for appeals that may be assigned to an attorney adjudicator and those appeals could also benefit from CMS, the IRE, or the Part D plan sponsor participation in the proceedings. We did not propose to limit the number of participants in a hearing similar to proposed § 405.1010(d) because the ALJ has the discretion to deny a request to participate under § 423.1010 and may therefore deny a request to participate if the ALJ determines that a hearing would have sufficient participant involvement or does not need participant involvement.

We proposed at § 423.2010(d) to consolidate current § 423.2010(d) through (f), to address the roles and responsibilities of CMS, the IRE, or the Part D plan sponsor as a participant. Specifically, we proposed at § 423.2010(d)(1) to generally incorporate current § 423.2010(d), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we proposed in § 423.2010(d)(1) that participation may include filing position papers "and/or" providing testimony to emphasize that either or both may be done, and to remove the limitation that testimony must be written because participation may include providing oral testimony during the hearing. We proposed at § 423.2010(d)(2) to incorporate current § 423.2010(e), which provides that when participating in a hearing, CMS, the IRE, or the Part D plan sponsor may not be called as a witness during the hearing and, thus, are not subject to examination or cross-examination by the enrollee at the hearing. However, to be clear about how an enrollee and the ALJ may address statements made by CMS, the IRE, or the Part D plan sponsor during the hearing given that limitation, we also proposed in § 423.2010(d)(2) that the enrollee may rebut factual or policy statements made by the participant, and the ALJ may question the participant about its testimony.

We proposed at § 423.2010(d)(3) to incorporate current § 423.2010(f) with certain revisions as discussed below. Current § 423.2010(f) states that CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the time frame designated by the ALJ.

We proposed in § 423.2010(d)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation requests in proposed 423.2010(b), and require that copies of position papers and written testimony be sent to the enrollee. Specifically, we proposed in § 423.2010(d)(3) that, unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a CMS, the IRE, or the Part D plan sponsor position paper or written testimony must be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled, or no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing. We proposed to add "written testimony" to recognize that CMS, the IRE, or the Part D plan sponsor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We proposed to require that position papers and written testimony be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also proposed to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing (unless the ALJ grants additional time) to help ensure the ALJ and the enrollee have an opportunity to review the materials prior to the hearing. Similar to proposed § 405.1010(c)(3)(iii), we also proposed at § 423.2010(d)(3)(ii) that a copy of the position paper or written testimony must be sent to the enrollee, and at § 423.2010(d)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of the position paper or written testimony to the enrollee or fails to submit the position paper or written testimony within the established time frames. This would help ensure CMS, IRE, or Part D plan sponsor position papers and

written testimony are submitted timely and shared with the enrollee.

Currently, there are no provisions in § 423.2010 to address the possibility of CMS, the IRE, and/or the Part D plan sponsor making an invalid request to participate. We proposed to revise § 423.2010(e) to add new provisions to establish criteria for when a request to participate may be deemed invalid and provide standards for notifying the entity and the enrollee when a request to participate is deemed invalid. We proposed in § 423.2010(e)(1) that an ALJ or attorney adjudicator may determine a request to participate is invalid if the request to participate was not timely filed or the request to participate was not sent to the enrollee. We stated that this would help ensure that CMS, the IRE, and/or the Part D plan sponsor make timely requests to participate and inform the enrollee of requests. To provide notice to the entity and the enrollee that a request to participate was deemed invalid, we proposed in § 423.2010(e)(2) to require that a written notice of an invalid request be sent to the entity that made the request and the enrollee. We proposed in § 423.2010(e)(2)(i) that if no hearing is scheduled for the appeal or the request was made after the hearing occurred, the notice of an invalid request would be sent no later than the date the decision, dismissal, or remand order is mailed. We proposed in § 423.2010(e)(2)(ii) that if a non-expedited hearing is scheduled for the appeal, written notice of an invalid request would be sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We proposed in § 423.2010(e)(2)(iii) that if an expedited hearing is scheduled for the appeal, oral notice of an invalid request must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We proposed to require the oral notice for expedited hearings because the very short time frames involved in expedited hearing proceedings often do not allow for delivery of a written notice and the oral notice will help ensure the entity is made aware of the invalid request prior to the hearing.

iii. Section 405.1012: When CMS or Its Contractors May Be a Party to a Hearing

Current § 405.1012(a) states that CMS and/or its contractors may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary. Current § 405.1012(b) states

that CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. Current § 405.1012(c) states that, when CMS or its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ. Finally, current § 405.1012(d) states that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party. As stated previously, we proposed significant changes to § 405.1012.

Current § 405.1012 does not limit the number entities that may elect to be a party to the hearing. We stated in the proposed rule that this has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we proposed at § 405.1012(a)(1), except as provided in proposed paragraph (d) discussed below, to only allow either CMS or one of its contractors to elect to be a party to the hearing (unless the request for hearing is filed by an unrepresented beneficiary, which precludes CMS and its contractors from electing to be a party to the hearing). Current § 405.1012(b) states that CMS or a contractor advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. We proposed at § 405.1012(a) to incorporate and revise a portion of current § 405.1012(b), to require that an election to be a party must be filed no later than 10 calendar days after the QIC receives the notice of hearing, because notices of hearing are sent to the QIC in accordance with § 405.1020(c) (the remaining portion of current § 405.1012(b) is incorporated with revisions into proposed § 405.1012(b), as discussed below).

Current § 405.1012 does not have a provision similar to current § 405.1010(a), which states that an ALJ may request that CMS and/or one or more of its contractors participate in the proceedings, but current § 405.1012(d) does provide that the ALJ may not require CMS or a contractor to enter a

case as a party or draw any adverse inference if CMS or a contractor decided not to enter as a party. In practice, ALJs do at times request that CMS or a contractor elect to be a party to the hearing, in conjunction with a request for participation under current § 405.1010(a). To align the provisions and reflect ALJ practices, we proposed at § 405.1012(a)(2) to state that an ALJ may request but not require CMS and/or one or more of its contractors to be a party to the hearing. We also proposed in § 405.1012(a)(2) to incorporate current § 405.1012(d) to provide that that an ALJ cannot draw any adverse inferences if CMS or a contractor decides not to enter as a party.

We proposed at § 405.1012(b) to address how CMS or a contractor elects to be a party to the hearing. We proposed to follow the same process in current § 405.1012(b) so that under proposed § 405.1012(b), CMS or the contractor would be required to send written notice of its intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant.

We proposed to set forth the roles and responsibilities of CMS or a contractor as a party in § 405.1012(c). Proposed § 405.1012(c)(1) would incorporate current § 405.1012(c) with some changes in wording, both of which provide that as a party to the hearing, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses, or cross-examine the witnesses of other parties. We proposed in § 405.1012(c)(2) to include written testimony, such as an affidavit or deposition, in the provision; establish deadlines for submission of position papers, written testimony, and evidence; and require that copies of position papers, written testimony, and evidence be sent to the parties that were sent a copy of the notice of hearing. Specifically, we proposed in § 405.1012(c)(2)(i) and (c)(2)(ii) that any position papers, written testimony, and evidence must be submitted no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the materials, and copies must be sent to the parties who were sent a copy of the notice of hearing. We proposed to add “written testimony” to recognize that CMS or a contractor may submit written testimony, in addition to providing oral testimony at a hearing. We also proposed to require that position papers, written testimony, and/or evidence be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time),

and that copies be submitted to the parties sent notice of the hearing, to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Current § 405.1012 does not address the consequence of failure to submit a position paper or evidence in accordance with the section. We proposed in § 405.1012(c)(2)(iii) that a position paper, written testimony, and/or evidence would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit the position paper, written testimony, and/or evidence within the established time frames. We stated in the proposed rule that this would help ensure CMS or contractor position papers and evidence are submitted timely and shared with the parties.

As discussed above, current § 405.1012 does not limit the number of entities (that is, CMS and its contractors) that may elect to be a party to the hearing and, as also discussed above, we proposed to revise § 405.1010 and 405.1012 to limit the number of entities that participate in a hearing unless an ALJ determines that an entity's participation is necessary for a full examination of the matters at issue. We proposed to revise § 405.1012(d)(1) to provide that if CMS and one or more contractors, or multiple contractors file elections to be a party to a hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3) (and as such may file position papers and provide written testimony to clarify factual or policy issues in the case, but may not participate in the oral hearing unless the ALJ grants leave to the entity to participate in the oral hearing in accordance with § 405.1010(d)(3)). Similar to proposed § 405.1010(d)(3), we also proposed in § 405.1012(d)(2) that, notwithstanding the limitation in proposed § 405.1012(d)(1), an ALJ may grant leave for additional entities to be parties to the hearing if the ALJ determines that an entity's participation as a party is necessary for full examination of the matters at issue.

We stated in the proposed rule that we believed allowing the first entity to file an election after a notice of hearing is issued to be a party to the hearing is administratively efficient and provides an objective way to determine which entity is made a party based on the competing elections, while providing an opportunity to participate in the appeal

by filing a position paper and/or written testimony under § 405.1010 for those that file later in time, or to be made a participant or party to the hearing by the ALJ under the ALJ's discretionary authority under proposed §§ 405.1010(d)(3) and 405.1012(d)(2). We considered an alternate proposal of the first entity that had elected participant status under § 405.1010, if any, being given priority for being made a party to the hearing, but stated that we believed that would result in other entities making a party election being uncertain whether they will be made a party to the hearing until as few as 5 days prior to the hearing (assuming the notice of hearing is sent 20 days prior to the scheduled hearing, as required by § 405.1022(a), the QIC receives the notice of hearing 5 days later, and the entity or entities responding to the notice of hearing can make their election as late as 10 calendar days after the QIC's receipt of the notice, leaving only 5 days prior to the hearing). We also considered a process by which the ALJ would assess which entity making a party election would be most helpful to the ALJ at the hearing, or in the alternative, permitting all entities that filed a party election to be made a party to the hearing unless the ALJ determined an entity is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in CMS, contractors and parties being uncertain of which entities will be parties to the hearing until shortly before the hearing. We solicited comments on the alternatives considered above.

Finally, we proposed to add new § 405.1012(e) to address the possibility of CMS or a contractor making an invalid election. Proposed § 405.1012(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue. We stated that this would help ensure that CMS and its contractors make timely elections and inform parties of elections, and also provide a mechanism to address an election when the request for hearing was filed by an unrepresented beneficiary or when another entity has already filed an election to be a party to the hearing. To

provide notice to the entity and the parties that an election was deemed invalid, we proposed in § 405.1012(e)(2) to require that a written notice of an invalid election be sent to the entity that made the election and the parties who were sent the notice of hearing. We proposed in § 405.1012(e)(2)(i) that if the election was submitted after the hearing occurred, the notice of an invalid election would be sent no later than the date the decision, dismissal, or remand notice is mailed. We proposed in § 405.1012(e)(2)(ii) that if the election was submitted before the hearing occurs, the written notice of invalid election would be sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice would be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing would be sent as soon as possible after the oral notice is provided.

Provided below are summaries of the specific comments we received relating to our proposed revisions to §§ 405.1010, 405.1012, and 423.2010, and responses to these comments. Because many commenters submitted comments that touched on all three proposals, we are collectively addressing in this section comments that related to sections III.A.3.f.i, ii, and iii of the proposed rule:

*Comment:* We received five comments expressing support of proposed §§ 405.1010, 405.1012, and 423.2010 and discussing some specific benefits that commenters believed the proposal will have on the hearing process. One commenter noted that the clarifications in the proposed rules will help appellants better prepare their arguments if they are aware that CMS or a contractor will be participating in the hearing process. Several commenters noted that the proposed limitation on the number of entities that may be a party to a hearing and participate in the oral hearing will eliminate unnecessary delays and duplicative and redundant argument and testimony that currently occur when multiple contractors elect or request to be a participant or party to the same hearing. One commenter indicated that the proposals will make scheduling hearings easier. One commenter indicated that the proposed changes will help ALJs make better use of limited time, allowing them to hear more cases. The same commenter noted that because the quality and credibility of the evidence, rather than the quantity, influences decision making, having more than one contractor present

during the hearing does not add value to the process.

*Response:* We thank the commenters for their support and agree that the proposed rules set necessary parameters that will help ensure that hearings involving CMS or a contractor as a participant or a party will be as efficient as possible and that the expectations and roles of those entities when they elect either status are clear.

*Comment:* Two commenters suggested that the rules should go further and prohibit CMS or one of its contractors from participating in the proceedings on a request for an ALJ hearing if CMS or one of its contractors has entered the appeal as a party. The commenters argued that the rights of a party encompass all the rights of a participant and it is unclear what additional value would be gained from allowing another entity to enter as a participant in such instances.

*Response:* Section 405.1010(d)(1), as finalized in this rule, states that if CMS or a contractor has been made a party to a hearing in accordance with § 405.1012, no entity that elected to be a participant in the proceedings in accordance with § 405.1010 (or that elected to be a party to the hearing but was made a participant in accordance with § 405.1012(d)(1) as finalized in this rule) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case. We believe that involvement by CMS or its contractors in the proceedings on a request for hearing may be beneficial and can assist in clarifying factual and policy issues and providing a fuller examination of the matters at issue that may be necessary to resolve appeals.

While the interest of administrative efficiency supports limiting participation at the oral hearing, we do not believe the same rationale applies to position papers and written testimony. The submission of position papers and written testimony adds minimal burden to the appeals process, may assist with clarifying facts and policy, and allows for a fuller presentation of the appeal. While it is possible that there may be some repetition in the written submissions, we believe that there is potential added value in permitting contractors to submit position papers and written testimony for consideration in this situation.

*Comment:* Two commenters that currently hold QIC contracts submitted comments opposed to the limitations placed on CMS and its contractors participating in an oral hearing pursuant to § 405.1010(d). According to one commenter, contractors often bring a

unique perspective to ALJ hearings and participation of all interested parties and participants allows for a robust and complete presentation of the case and often yields greater consistency in decisions. The commenter noted that given the involvement of multiple contractors in any given appeal prior to the OMHA level—such as MACs, Zone Program Integrity Contractors (ZPICs), and Recovery Auditors—one contractor cannot always effectively address all issues in an appeal, and argued that when multiple contractors participate in an oral hearing, the contractors coordinate their presentations so that they do not repeat testimony when they are in agreement to keep the hearing duration at a minimum. The second commenter argued that the limitations proposed in § 405.1010(d) would significantly impact the QIC's ability to meet its contractual requirements for oral non-party participation at hearings and that QICs, in response, would have to elect participation in many additional hearings in order to meet those requirements, placing an administrative burden on OMHA to manage the participation requests.

*Response:* We agree that there is value in having CMS and its contractors involved in the proceedings at OMHA as participants, but we believe that limiting the number of participants at the oral hearing while still providing CMS and its contractors with an opportunity to share their unique perspectives through position papers and written testimony strikes an appropriate balance between administrative efficiency and obtaining as much information as possible for the ALJ to render a decision on the matter. In addition, we note that § 405.1010(d)(3), as finalized in this rule, also permits additional participation in the oral hearing if the ALJ determines that a precluded entity's participation is necessary for a full examination of the matters at issue such as cases involving multiple MAC jurisdictions, significant dollar amounts at issue, extrapolation, and pre-pay or post-pay audits. Finally, with respect to concerns related to a contractor's ability to satisfy its contractual obligations, after the final rule is effective, CMS intends to make necessary contract modifications to account for the provisions of this final rule related to contractor participation, and encourage the contractors to coordinate participation in the hearings.

*Comment:* We also received one comment, jointly submitted by four entities holding DME MAC contracts, opposing the limitation on the number of contractor participants at oral

hearings. The commenters noted that in the case of a large appeal involving statistical sampling and extrapolation or consolidated hearings, multiple DME MACs may have processed claims that are at issue in the appeals, and the restriction on the number of participants at the oral hearing makes it impossible for each to have its "day in court." The commenters argued that the contractor permitted to participate at the oral hearing may not have access to information on the beneficiaries and claims from other DME MAC jurisdictions and could not present any argument or defense for those denials. Finally, the commenters noted that it is impossible for those contractors who are not permitted to participate at the oral hearing to anticipate and refute arguments in a position paper written in the absence of knowledge of the appellant's defense.

*Response:* Section 405.1010(d)(3), as finalized in this rule, provides that if CMS or a contractor is precluded from participating in the oral hearing under the provisions limiting the number of participants, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. This paragraph provides the ALJ with necessary discretion to permit additional participants at the hearing in situations such as the ones noted above by the commenter, where multiple contractor participants at hearing may be necessary for a full examination of the issues. We provided examples above highlighting when an ALJ may find it necessary to exercise the discretion afforded to the ALJ in § 405.1010(d)(3). In one example, we indicated that when an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. In another example, we suggested that in overpayment cases involving statistical sampling and extrapolation, the ALJ may allow participation in the oral hearing by both the contractor that conducted the sampling who is necessary to address issues related to the sampling and extrapolation and another contractor that made an election to participate to clarify the policy and factual issues related to the merits of the claims in the sample. The examples presented by the commenter—cases involving statistical sampling and extrapolation or consolidated hearings in which multiple contractor jurisdictions are involved and a single contractor does not have

information on all beneficiaries or claims involved—are similar instances when the ALJ may use his or her discretion to permit additional participants at the oral hearing because the additional participants may be necessary for a full examination of the matters at issue.

With respect to the commenter's concern that the contractor permitted to participate in the oral hearing may not have access to information on the beneficiaries and claims from other DME MAC jurisdictions and could not present any argument or defense for those denials, we note that even when a contractor is not permitted to participate in the oral hearing under § 405.1010(d)(1), the contractor can still submit position papers and written testimony, which may provide helpful information to the contractor participating in the oral hearing. However to help further ensure that CMS or a CMS contractor that has elected party status is able to fully represent the position of CMS in cases where the entity that elected party status does not have information on all beneficiaries or claims involved, or where the entity that has elected party status deems it necessary to call another CMS contractor as a witness, we are amending proposed § 405.1010(d)(3) to provide that CMS or a contractor that is precluded from participating in the oral hearing under paragraph § 405.1010(d)(1) may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with § 405.1012. We expect the need for CMS or a contractor as a party to call another CMS contractor as a witness would be an infrequent occurrence, and believe this approach strikes the appropriate balance between administrative efficiency and addressing the commenter's concerns.

With respect to the commenter's concern that position papers and written testimony will be inadequate to refute arguments that are made at the hearing, we note that the role of participants, both in written submissions and participating in the oral hearing, is to provide testimony to clarify factual or policy issues, and does not include calling witnesses or cross-examining the witness of a party to the hearing. In addition, we believe that CMS and its contractors are already familiar with the appellant's arguments based on the contractors' review of the record and involvement in the lower-level appeal decisions or the initial determination. Accordingly, we believe that contractors have generally set forth their positions on those arguments in the lower-level decisions or will have an



opportunity to do so through the written submissions to OMHA.

*Comment:* One commenter requested that OMHA institute a notification process to notify contractors of which entity submitted its election to participate first and, therefore, is permitted to participate in the oral hearing. The commenter noted that timely notification is important because it takes additional time and resources to plan for participation at the hearing. The commenter also suggested that instead of adopting a rule in which the first entity to file a response to the notice of hearing may participate in the oral hearing, OMHA should give priority to MACs and QICs over RAs because initial determinations, redeterminations, and reconsiderations are formal steps in the appeals process.

*Response:* The proposed rules do not specifically address notification to the entities regarding whether they will participate at the oral hearing or participate by submission of position papers and/or written testimony. If a hearing is scheduled, the assigned ALJ will notify the contractors regarding their participation prior to the hearing. OMHA will develop a consistent notification process, including guidance on when notification to the contractors should be made and the method of delivery of such notification, which will be made part of the OCPM. The OCPM describes OMHA case processing procedures in greater detail, provides frequent examples to aid understanding, and it is accessible by the public on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)).

As discussed in the comment summary above, we considered alternatives to the proposed rule that the first entity to file a response to a notice of hearing be given priority for participating at the hearing, however we decided that giving the first entity priority is administratively efficient and provides an objective and clear way of determining which contractor is allowed to participate at the oral hearing. We do not agree with the commenter that OMHA should give priority to MACs and QICs over RAs as we believe, from our experience and from feedback we received from stakeholders, that there are valid and equal arguments why each of these entities' participation may be valuable in the proceedings. We again note that § 405.1010(d)(3), as finalized in this rule, would allow the ALJ to permit multiple participants to attend the hearing if the participation of multiple entities at the hearing would be necessary for a full examination of the matters at issue.

*Comment:* We received one comment in support of proposed § 405.1010(b)(3) allowing two distinct points in the adjudication process for contractors to elect to participate. However, the commenter suggested that the timing of the election periods specified in § 405.1010(b)(3)(i) and (ii) be calculated starting with notification to the contractor rather than notification to the QIC. The commenter indicated that notice to the QIC does not give equal notice to the contractors and that there are delays in the transmission of information regarding whether a request for hearing has been filed and when the case is advanced in the Medicare appeals case processing system from the QIC level to the OMHA level.

*Response:* We thank the commenter for its support of proposed § 405.1010(b)(3) and believe that by providing two distinct points governing the timing of an election to participate in the proceedings helps ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process. The proposed regulation on timing of the election to participate provides that if no hearing is scheduled, CMS or its contractors must make the election no later than 30 calendar days after the notification that a request for hearing was filed or, if a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing. We believe that the 30 calendar day and 10 calendar day timeframes set forth in § 405.1010(b)(3)(i) and (ii) (as finalized) provide adequate time for all contractors to receive notice and to file an election to be a participant. With respect to the commenter's concern regarding notice to the contractors when a request for hearing is filed, in addition to the constructive notice provided to the QICs, OMHA and CMS will begin the process of modifying contract provisions with regards to hearing request notifications after the effective date of this final rule. CMS and OMHA will develop a process to notify the contractors of the hearing requests and CMS will convey the process to the contractors when it is ready to be operationalized.

Pursuant to § 405.1020(c)(1) (as finalized in this rule), if a hearing is scheduled, the ALJ would send notice of the hearing to the QIC, to CMS and any contractor that the ALJ believes would be beneficial to the hearing, and, as discussed below, to CMS or any contractor that elected to participate in the proceedings in accordance with § 405.1010(b). Therefore, if a contractor has elected to participate in the

proceedings before a notice of hearing has been sent, under § 405.1020(c)(1), if a hearing is ultimately scheduled that entity will receive a copy of the notice of hearing directly from OMHA. While contractors not specified in § 405.1020(c)(1) will not receive a copy of the notice of hearing directly from OMHA, we believe that limiting the number of notices provided to those entities specified in § 405.1020(c)(1) is necessary to minimize the administrative burden on OMHA. Further, we do not believe that limiting the number of notices will compromise the interests of contractors because we plan to issue sub-regulatory guidance, including educational materials and contractual modifications that will establish processes to accommodate the regulatory changes. These processes will relate to timely notice, information sharing, and coordination among affected contractors that may have an interest in participating in the same hearing. CMS will begin the process of issuing sub-regulatory guidance and contractual modifications after the effective date of this final rule.

*Comment:* We received a comment asking whether the submission of a written notice of intent to participate will be the same for cases assigned to an attorney adjudicator and cases assigned to an ALJ, and whether the notice of intent to participate will be accepted in electronic form. The comment also asked, with respect to the filing of a notice of intent to participate prior to assignment of the appeal to an ALJ or attorney adjudicator, if the Chief ALJ will have only one designee and, if not, how contractors will know to whom to send the notices.

*Response:* The process for submission of a notice of intent to participate under § 405.1010(b) is the same regardless of whether the appeal is assigned to an ALJ or an attorney adjudicator. Rather, the distinctions in § 405.1010(b) regarding the notice of intent to participate are based on whether a notice of hearing has been issued and the timing of the election. After the final rule becomes effective, OMHA will develop consistent procedures for the receipt of notices of intent to participate in ALJ and attorney adjudicator proceedings, including specific instructions regarding where notices of intent to participate for appeals that are not yet assigned to an ALJ or attorney adjudicator should be directed. We will also consider including an option for submitting notices of the intent to participate in electronic form. These case processing details will be made part of the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and

procedures of OMHA. The OCPM describes OMHA case processing procedures in greater detail and is accessible to the public on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)).

*Comment:* We received two comments in support of proposed §§ 405.1010(c)(3) and 423.2010(d)(3), which place time frames on the submission of position papers and written testimony by CMS or its contractors, and by CMS, the IRE, and/or Part D plan sponsor, respectively, require that copies are sent to other parties, and provide that if the participating entities fail to submit the items within the specified time frame or to send copies to the other parties, then the position paper and/or written testimony will not be considered in deciding the appeal. The commenters recommended that the time frames in proposed §§ 405.1010(c)(3) and 423.2010(d)(3) for submitting position papers and written testimony also apply to the requirement to send copies to other parties. We also received one comment requesting that the same revision be made to § 405.1012(c)(2)(ii) regarding the time frame for sending to the other parties copies of any position papers, written testimony, and evidentiary submissions that CMS or one of its contractors submits to OMHA as a party to the hearing.

*Response:* We thank the commenters for their support. We intended that the time frames in §§ 405.1010(c)(3)(i), 423.2010(d)(3)(i), and 405.1012(c)(2)(i) also be applied to copies of position papers and written testimony sent to the other parties. Given this was not clear to the commenters, we are modifying the language in proposed §§ 405.1010(c)(3)(ii), 423.2010(d)(3)(ii), and 405.1012(c)(2)(ii) to better convey the requirement. We are revising § 405.1010(c)(3)(ii) to state that a copy of any position paper or written testimony submitted to OMHA must be sent to the other parties within the same time frame specified in § 405.1010(c)(3)(i). Because § 405.1010(c)(3)(i) requires the submission to OMHA to be sent within 14 calendar days of an election to participate, if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled, unless the ALJ grants additional time, the requirement that the copies be sent to the other parties within these same time frames will ensure that the copies are also timely received by the parties. Similarly, we are revising § 423.2010(d)(3)(ii) to state that a copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent to the enrollee within the same time frames that it must

be submitted to OMHA as provided in § 423.2010(d)(3)(i)(A) and (B). Finally, we also are revising § 405.1012(c)(2)(ii) to state that a copy of any position paper, written testimony, or evidence submitted to OMHA must be sent to the other parties within the same time frame specified in § 405.1012(c)(2)(i).

*Comment:* We received one comment supporting the 14 calendar day time frame proposed in § 405.1010(c)(3)(i) for submitting a position paper or written testimony after an election to participate if no hearing is scheduled, but suggesting that the start for calculating the 14 calendar days should begin with “response to the contractor and not the QIC.”

*Response:* We thank the commenter for its support but believe that the commenter misinterpreted when the 14 calendar day time frame proposed in § 405.1010(c)(3)(i) begins. The time frame for submission of a position paper or written testimony specified in proposed § 405.1010(c)(3)(i) begins on the date of the contractor’s election to participate if no hearing has been scheduled, not on the date the QIC or the contractor receives the notice of hearing.

*Comment:* We received one comment that expressed concern that the stated time frame in § 405.1010(c)(3)(i), requiring the submission of CMS or contractor position papers and written testimony no later than 5 calendar days prior to the scheduled hearing, unless additional time is granted by the ALJ, is an unreasonably short period and does not allow sufficient time for an appellant to react to new arguments or proposed theories that may be contained in those written submissions prior to the hearing. The commenter suggested that this short time frame is unfavorable to appellants.

*Response:* Current § 405.1010 does not set forth specific time frames for submitting position papers and written testimony. Current § 405.1010(e) states only that CMS or its contractor must submit any position papers within the timeframe designated by the ALJ. ALJs, however, would often accept written submissions up to and including on the day of the hearing. We believe that the requirement to submit any position papers or written testimony not later than 5 calendar days prior to the scheduled hearing provides sufficient time for the ALJ and the parties to review the submissions prior to the hearing and will provide a clear and consistent time frame regarding these submissions. In addition, we believe that § 405.1010(c)(3)(iii) (as finalized in this rule), which provides that if CMS or a contractor fails to submit its

position paper or written testimony within the set time frames then the submissions will be excluded from consideration, provides additional protections that are favorable to appellants.

*Comment:* Another commenter noted that when CMS or its contractor “is called to provide position papers and written testimony” but fails to submit the position paper or written testimony on time, the entities should be required to provide the requested written submissions or provide a valid reason for why the requested information could not be provided. The commenter noted that the information may have a significant impact on the outcome of an appeal.

*Response:* We first want to clarify that, under the rules as finalized, when CMS or a contractor makes an affirmative election to participate and wishes to submit a position paper and/or written testimony, it must do so within the specified time frames provided in § 405.1010(c)(3)(i) or the submissions are excluded from consideration pursuant to § 405.1010(c)(3)(iii). We believe that providing time frames for submissions by CMS or its contractors when they elect to participate helps to ensure that any submissions are timely received and that appellants and other parties will have an opportunity to review them prior to the hearing, if a hearing is conducted. The comment suggests that the position paper and written testimony of concern was requested by the ALJ, however §§ 405.1010(a)(2) and 405.1012(a)(2) (both as finalized in this rule) provide that although an ALJ may request CMS and/or one of its contractors to participate in any proceedings before the ALJ, or to be a party at the hearing, the ALJ cannot require such participation or party status and cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings or to be a party at the hearing. The language set forth in proposed § 405.1010(a)(2) was not changed from the current regulations, but rather combines the rules currently found at § 405.1010(a) and (f). Similarly, the language in proposed § 405.1012(a)(2) was carried forward from current § 405.1012(d). We do not believe that the commenter’s suggestion of making the submissions mandatory or requiring that CMS or its contractor provide valid reasons for failing to submit certain requested written testimony is consistent with the established rule that an ALJ may not require that CMS or a contractor participate in the proceedings or be a

party at the hearing. The limited resources and broad programmatic responsibilities facing CMS and its contractors may not allow for participation or party status election in all appeals. We believe that CMS and its contractors must have some discretion in determining when election of participant or party status under §§ 405.1010 and 405.1012 is most appropriate given those resources and other responsibilities.

Finally, we disagree with the commenter's suggestion that when CMS or a contractor fails to provide requested position papers and/or written testimony that it will have a significant impact on the appeal. First, if an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successors under § 405.1034, as finalized in this rule. Second, CMS or its contractors will likely elect participation or party status in those appeals that involve more complex issues of fact or law and where their participation or party status will be most useful. Finally, while position papers and/or written testimony submitted by CMS or its contractors may be helpful in clarifying factual issues or policy, we do not believe that the failure to submit position papers or written testimony is likely to result in any negative impact on the appellant or other parties. The appellant and other parties obviously may still present their full testimony and arguments and the ALJ or attorney adjudicator will consider evidence in the administrative record as appropriate, including all administrative proceedings, prior to issuing a decision.

*Comment:* We received two comments supporting the clarification in proposed § 405.1010(c)(2) that even though CMS or its contractor is not subject to examination or cross-examination by the parties, the parties "may provide testimony to rebut factual or policy statements made by a participant, and the ALJ may question the participant about its testimony." The commenters requested that this language be modified to more affirmatively require that the parties be given the opportunity to provide testimony and to ensure that beneficiaries are made aware of this option at the hearing. The commenter also requested that CMS provide advocate education about this provision. We received one comment that made this same request with respect to the enrollee's ability to rebut factual or

policy statements made by CMS, the IRE, or the Part D plan sponsor participant in the course of Part D hearings as provided in proposed § 423.2010(d)(2).

*Response:* We thank the commenters for their support. We agree that the proposed language in both §§ 405.1010(c)(2) and 423.2010(d)(2) helps to clarify how a party and the ALJ may address statements made by participating entities during the hearing. However, we believe that the ALJ is in the best position to help ensure that a beneficiary or enrollee is aware of this option during the course of the hearing, and that ALJs may use their discretion to regulate the course of the hearing, including by affirmatively asking parties if they want to rebut factual or policy statements made by a participant during the hearing. We anticipate that OMHA ALJs will receive training on all the rules once they become effective, including the rules in §§ 405.1010(c)(2) and 423.2010(d)(2). We do not agree that additional revisions to the language in §§ 405.1010(c)(2) and 423.2010(d)(2) are necessary because the language as finalized in this rule provides the necessary protection while still balancing the right and role of the ALJ to control the hearing. CMS provides ongoing stakeholder education and anticipates that education regarding this provision and the other rules will be available after the rules are effective.

*Comment:* One commenter stated that although the regulations at § 405.1010(c)(2) provide that contractors participating in an ALJ hearing cannot be called as witnesses, the regulations should clarify that they cannot also voluntarily testify as a witness. The commenter noted that in its experience, Medical Directors of the contractors often participate in the hearings and offer commentary on the clinical judgment of the treating professionals, which the commenter views as inappropriate witness testimony. The commenter stated that if witness testimony is desired by a contractor, a witness must be identified and qualified, and the appellant must have the right to cross-examine the witness.

*Response:* We believe that § 405.1010(c) as finalized in this rule clarifies the roles and responsibilities of CMS and contractors who are participants at the oral hearing. We note that § 405.1010(c)(1) and (2), as finalized in this rule, incorporate the policies from current § 405.1010(c) and (d), providing that participants may file position papers or provide testimony to clarify factual or policy issues in a case, but may not call witnesses or cross-examine the witnesses of a party to the

hearing, and may not be called as a witness itself, with the exception we are finalizing in § 405.1010(d)(3) of this rule to allow CMS or a contractor that has been made a party to the hearing in accordance with § 405.1012 to call as a witness CMS or another contractor that has been precluded from participating in the hearing. Further, § 405.1010(c)(2), as finalized, now clarifies that a participant is also not subject to examination or cross examination by the parties and includes a new provision that clarifies that a party may rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony. Although the commenter suggests that contractor participants often do not follow the limitations on participation set by the regulations, including by voluntarily testifying as witnesses, we believe that the additional clarification in these provisions regarding the roles and responsibilities of CMS or a contractor as a participant will help ensure that participants only provide testimony to clarify factual or policy issues in a case. In circumstances in which a party believes that a participant is providing testimony outside of the scope of clarifying factual or policy issues, the party may raise the issue with the ALJ.

*Comment:* Two commenters recommended that the rules clarify how an ALJ should proceed if a contractor fails to make an appearance at the hearing after notifying the ALJ and appellant(s) of its intention to be a participant or party to the oral hearing. The commenters recommended that if CMS or a contractor fails to appear at a hearing, "no further participation or party status should be permitted for that entity."

*Response:* If CMS or a contractor is a party or participant to the oral hearing but does not appear at the scheduled time and place of the hearing after notice of the hearing has been provided, the hearing may proceed without that entity. While the involvement of CMS and/or a contractor in the hearing as either a participant or a party is permitted by §§ 405.1010 and 405.1012, the regulations do not require or guarantee such participation or party status, and thus the election of participant or party status, and the extent of participation, is at the discretion of CMS and its contractors. We believe this is clear in the regulations as finalized at §§ 405.1010(a), 405.1012(a), and 423.2010(a), and that the regulations do not need to be further clarified in this regard. Therefore, we believe that if CMS or a contractor that has elected to

be a participant or a party at the hearing fails to appear at the hearing and notice of the hearing time and place has been duly provided, then the ALJ may proceed without that entity. Also, there is no provision that excludes the entity from further participation in the proceedings if there are opportunities for such participation, and we do not believe it would be appropriate to limit further participation after an election is made, as we believe that CMS and contractor participation may be beneficial and can assist in clarifying factual or policy issues in a case. In addition, there may be administrative reasons, including scheduling conflicts, which prevent an entity from appearing at the hearing at the last minute. For the same reasons discussed above, we believe that any position papers or written testimony that had been previously submitted in accordance with the time frames in §§ 405.1010(c)(3) and 405.1012(c)(2) may still be considered by the ALJ.

*Comment:* One commenter requested the rules be revised to add a requirement making CMS's or its contractor's attendance mandatory "when one of the issues in the hearing concerns that entity's violation or non-compliance with existing statute or CMS policy." The commenter suggested that by inviting CMS or its contractor to the hearing, the entities are given an opportunity to recognize that they are in violation and will have a chance of correcting the situation.

*Response:* Section 405.1010(a)(2), as finalized in this rule, provides that an ALJ may request that CMS and/or one of its contractors participate in the proceedings before the ALJ, including the oral hearing, if any, but also provides that the ALJ may not require the participation and may not draw any adverse inferences if CMS or the contractor decides not to participate. These provisions carry forward policies in current § 405.1010(a) and (f). The limited resources and broad programmatic responsibilities facing CMS and its contractors may not allow for participation or party status election in all appeals. We believe that CMS and its contractors must have some discretion in determining when election of participant or party status under §§ 405.1010 and 405.1012 is most appropriate given those resources and other responsibilities. Finally, it is not clear what the commenter means when he suggests that "one of the issues in the hearing concerns that entity's violation or non-compliance with existing statute or CMS policy." The ALJ scope of review is on the issues related to the appealed claim in accordance with

§ 405.1032. If the appellant believes the claim was denied in error as a result of non-compliance with relevant authority, such as a statute or regulation, or authority that is owed substantial deference, such as LCDs and program memoranda, those arguments should be articulated for the ALJ to consider in adjudicating the appealed claim. It is not necessary that CMS or a contractor be present for the ALJ to consider that argument and make a de novo determination applying the authority. On the other hand, if the commenter is suggesting that CMS or a contractor needs to be present at hearing for the ALJ to explain to that entity why that entity's decision constituted a "violation or non-compliance with existing statute or CMS policy," we do not agree that this is necessary because the ALJ's decision and rationale will be explained in the ALJ's written decision on the case, a copy of which is sent to the QIC in accordance with § 405.1046(a)(1) as finalized in this rule, and therefore available to CMS and its contractors. OMHA ALJs are responsible for administering hearings to resolve coverage and payment disputes, not to provide CMS or contractor education, and we do not believe that mandating CMS or a contractor to attend the hearing to address the appellant's assertions furthers the hearing process.

*Comment:* One commenter pointed out that under the proposed regulations no actual notice would be provided to CMS contractors when appeals are filed, and the "30-day constructive notice window" is the only opportunity for a contractor to participate in an appeal that could be assigned to an attorney adjudicator. The commenter stated that under the proposed rule, an ALJ hearing notice is the only actual notice to the contractors and the only opportunity for contractors to appear as parties. The commenter suggested that the proposed rule may be "a step backward in the important area of program integrity."

*Response:* We do not agree with the commenter and believe that the rules as finalized make necessary clarifications in defining when and how CMS or its contractors may elect, or request (for Part D appeals), to participate in the proceedings on a request for an ALJ hearing. Current § 405.1010 provides that CMS or its contractors may elect to be a participant within 10 calendar days of receiving the notice of hearing. Current § 423.2010 requires CMS, the IRE, or the Part D plan sponsor to request participation no later than 5 calendar days after receipt of the notice of hearing for a non-expedited hearing, or 1 calendar day after receipt of the notice of hearing for an expedited

hearing. Neither current rule specifically addresses appeals for which a hearing is not scheduled. Sections 405.1010(b) and 423.2010(b), as finalized, clarify that CMS or its contractors may elect or request participant status in proceedings even if a hearing is not conducted or is not necessary, with the applicable limitations and timeframes to help ensure that an election or request is filed in a timely manner after notification that a request for hearing is filed. We believe that, as finalized, §§ 405.1010(b) and 423.2010(b) provide necessary clarity for contractors in electing or requesting participation in appeals for which no hearing is scheduled, and in providing such clarification, may encourage additional participation in such proceedings and therefore support program integrity. In response to the commenter's concern that the only notice provided to CMS contractors when a request for hearing is filed is a constructive notice to the QICs, we note that OMHA and CMS plan to establish a process for notification to CMS contractors that a request for hearing has been filed, and we will communicate that process to the contractors after the effective date of the rule. As this is an internal process, we are not including this process in the regulations, because to do so would limit our flexibility to establish and change business processes and take advantage of emerging technologies through operational policies. The APA permits OMHA to adopt internal business processes without notice and comment rulemaking.

*Comment:* One commenter asked OMHA to specify what sort of notice would be given to the Part D plan sponsor when no notice of hearing is issued, and what would be the acceptable forms of communication when the Part D plan sponsor elects to participate in the proceedings when no notice of hearing is required, including in appeals assigned to an attorney adjudicator.

*Response:* OMHA and CMS plan to establish a process for notification to Part D plan sponsors that a request for hearing has been filed, and CMS will communicate that process to the Part D plan sponsors after the final rule becomes effective.

In response to the commenter's question regarding acceptable forms of communication, § 423.2010(b)(1), as finalized in this rule, provides that, if the Part D plan sponsor requests participation before it receives notice of hearing, or when no notice of hearing is required, the Part D Plan "must send written notice of its request to

participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate." Written communication may be mailed or fax. However, faxes must be sent in accordance with procedures to protect personally identifiable information.

*Comment:* We received two comments from CMS contractors noting that the initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed as set forth in proposed § 405.1010(b)(3)(i) will require additional work and resources for those entities to monitor requests for hearings being filed with OMHA. One comment stated that the proposed rules create additional work that may not be productive because QICs will have to screen cases appealed to OMHA for potential participation election even though those cases may never be heard, may be dismissed on procedural grounds, or may be withdrawn before a hearing is scheduled, which is a larger number of cases than those currently screened by contractors upon receipt of an ALJ's notice of hearing. Another comment noted that although it is possible for DME MACs to locate cases that have been appealed beyond the QIC, the process of researching the lists of appealed cases and selecting cases for which an election of participation is desired is not part of those entities' normal work structure. Both comments noted that additional resources, including as one commenter indicated, increased "visibility" of appeals filed at the OMHA level in the Medicare appeals case management system, and/or additional manpower, would be necessary to monitor cases appealed to OMHA. One comment stated that the DME MACs are only funded for small staffs to address ALJ appeals and may not have the resources to monitor and respond to the greater volume of appeals that may be anticipated after these rules are effective.

*Response:* While § 405.1010(b)(3)(i) as finalized in this rule may require increased coordination and perhaps shared resources among CMS and its contractors to monitor requests for hearing being filed at OMHA for possible participation election, we do not believe that these administrative concerns outweigh the benefits of § 405.1010 as finalized in this rule, or that the final rules would impose

unreasonable burdens on CMS or its contractors. We believe § 405.1010 as finalized adds necessary clarifications on CMS and contractor participation, and encourages participation in a greater number of appeals by clarifying that CMS and contractors may participate in appeals for which a hearing is not scheduled. However, § 405.1010 as finalized does not require a contractor to make an election or request participation, so while participation is encouraged and permitted, the rules do not obligate CMS or its contractors to perform additional work or expend any additional resources. The limited resources and broad programmatic responsibilities facing CMS and its contractors likely will not allow for participation in all appeals, so CMS and its contractors will use their discretion in determining when election of participant status is most appropriate. With regard to the commenter's concern that electing participant status for cases that have not been scheduled for a hearing would be outside DME MACs' normal work structure, CMS will address modifications to systems, contractor coordination, and contractor resources in guidance outside of this rule. If necessary, after the final rule is effective, CMS will make the necessary contract modifications to account for the provisions of this final rule.

*Comment:* Another comment from one of the entities that currently holds a QIC contract indicated that proposed § 405.1010(b)(1) would create scheduling difficulties for contractors that may be electing to participate in a hearing before they receive notice of the hearing date and time. The commenter argued that even under the current rules, contractors often have to choose between cases for participation because hearing dates and times with different ALJs conflict or overlap. The commenter noted that in practical terms, there is a large amount of time between when a request for hearing is filed and eventual assignment and scheduling of a hearing, and that it would be extremely challenging, if not impossible, for the QIC to plan for attendance at a hearing of unknown date and time.

*Response:* Although § 405.1010(b)(1) as finalized in this rule permits CMS or a contractor to elect to participate in the proceedings on a request for an ALJ hearing before receipt of a notice of hearing or when a notice of hearing is not required, if a hearing is then scheduled, the participating entity is not obligated to attend the hearing and if it has not already filed a position paper and/or written testimony, it may do so up to 5 calendar days prior to the

hearing. Moreover, if a hearing is ultimately scheduled, any entity that has already elected to participate in the proceedings will receive a notice of hearing pursuant to § 405.1020(c)(1) as finalized in this rule, and will have at that time notice of the scheduled hearing date and time. If the entity's schedule allows and the entity still wishes to participate at the oral hearing, it may file a response to the notice of hearing. If the scheduled hearing date and time does create a scheduling conflict for that entity, the entity may still elect to participate in the proceedings by submission of position papers or written testimony no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the position paper or written testimony.

*Comment:* One commenter requested clarification on the recourse available to a DME MAC if it elects to be a participant in an appeal and the hearing is scheduled for a date and/or time that contractor is unable to attend, and what effect the contractor's withdrawal from participation due to a schedule conflict would have on the decision of the ALJ or attorney adjudicator.

*Response:* Consistent with § 405.1020(e), CMS or a contractor that has elected participant status cannot request a change in the scheduled date or time of the hearing (unlike CMS or a contractor that has elected party status). However, the contractor may respond to the notice of hearing by indicating that it will not be able to attend due to a scheduling conflict without any adverse inference on the part of the ALJ as provided in § 405.1010(a)(2), and submit a position paper and/or written testimony for consideration within the time frame set forth in § 405.1010(c)(3).

*Comment:* We received two comments, one from an entity that currently holds a QIC contract and one from the four entities that currently hold the DME MAC contracts, quoting the language in proposed § 405.1010(b)(1) regarding how CMS or its contractors may make an election to participate "when a notice of hearing is not required" and indicating that it was unclear when a notice of hearing would not be required for a case.

*Response:* Under our regulations as finalized in this rule, a notice of hearing is not required for any case in which an on-the-record decision may be issued pursuant to § 405.1038, including: When an ALJ or attorney adjudicator determines the evidence in the record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, unless CMS or a contractor has

elected to be a party pursuant to § 405.1012 (as provided in § 405.1038(a)); when all parties who would be sent a notice of hearing indicate in writing that they do not wish to appear before an ALJ at a hearing (as provided in § 405.1038(b)(1)(i)); when the appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing and there are no other parties who would be sent a notice of hearing and who wish to appear (as provided in § 405.1038(b)(1)(ii)); or if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating that the item or service should be covered or payment may be made such that an ALJ or attorney adjudicator issues a stipulated decision in favor of the appellant or other liable parties (as provided in § 405.1038(c)).

*Comment:* We received the following questions from the four entities that currently hold the DME MAC contracts regarding administrative and procedural mechanisms related to proposed § 405.1010: (1) “will the request for hearing contain a list of all parties to whom a response should be sent;” (2) what mechanisms will be in place to assist with the assignment of cases to OMHA adjudicators in a timely manner; (3) how quickly after a request for hearing has been filed will it be assigned a firm hearing date; and (4) when and how will the DME MAC contractor become aware of that firm hearing date?

*Response:* DME MACs would not typically receive a copy of an appellant’s request for hearing (see § 405.1014(d), as finalized in this rule). Furthermore, § 405.1010(b)(1), as finalized in this rule, provides that if CMS or a contractor elects to participate in the proceedings before a notice of hearing is sent, or when a notice of hearing is not required, then the contractor must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the appeal is not yet assigned, and the parties who were sent a copy of the notice of reconsideration. Therefore, we believe the commenter may have intended to ask whether the notice of reconsideration (as opposed to a request for hearing) contains a list of all parties to whom an election to participate would be sent under § 405.1010(b)(1), as finalized in this rule. Under § 405.976(a)(1)(i), the QIC generally sends notice of the reconsideration to all parties at their last known address, and current QIC practice involves listing all the parties to whom the notice of

reconsideration was sent in either the address block or the courtesy copy section of the notice. Therefore, CMS or a CMS contractor need only look to the notice of reconsideration to determine which parties were sent a copy of the notice of reconsideration, and send a copy of its election to participate to the same parties.

Proposed § 405.1010 does not address the mechanisms for assignment of cases to OMHA adjudicators. OMHA’s case assignment process is subject to the priority of the case (to help ensure appeals filed by beneficiaries are adjudicated as quickly as possible, OMHA designates these appeals as priority appeals, with some exceptions), OMHA’s pending workload, and the availability of an adjudicator. More details on the OMHA case assignment process are available in the OCPM, which is accessible on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)). Contractors and others may determine whether a case has been assigned to an OMHA adjudicator and, if it is assigned, the assigned OMHA adjudicator, using AASIS, which also can be accessed through the OMHA Web site.

Similarly, proposed § 405.1010 does not address the length of time between when an appeal is filed and when a hearing date will be selected. The length of time between when an appeal is filed and when a hearing date is selected will vary based on how quickly the case is assigned to an OMHA ALJ, because only OMHA ALJs may conduct hearings, and the assigned ALJ’s availability and docket of other cases. Because this time is subject to significant variation based on the stated factors, we cannot provide a generally applicable estimate.

If and when a hearing is scheduled, the ALJ will issue a notice of hearing consistent with § 405.1022 to the parties and other potential participants provided for in § 405.1020(c), including, among others, to the QIC that issued the reconsideration and CMS or any contractor that the ALJ believes would be beneficial to the hearing. In consideration of the commenter’s question regarding when and how the DME MAC will become aware of the hearing date if the request for hearing is only sent to the QIC that issued the reconsideration, DME MACs and other non-QIC contractors would be notified of the hearing date by the QIC that issues the reconsideration in accordance with CMS instructions to QICs for notifying other contractors of a scheduled ALJ hearing. However, we believe it is also appropriate for the notice of hearing to be sent to CMS or any contractor that elected to participate in the proceedings consistent with

§ 405.1010(b), and we are revising our proposal at § 405.1020(c)(1) to require this. Thus, a non-QIC contractor will receive notice of the hearing either directly from OMHA, if the contractor has elected to participate before receipt of a notice of hearing or if the ALJ believes the non-QIC contractor would be beneficial to the hearing, or it will receive notice of the hearing from the QIC if it elects to participate after notice of hearing is sent.

*Comment:* We received one comment requesting clarification of the language in proposed § 405.1012(a)(2), which in the commenter’s opinion, suggests that an ALJ may request that CMS and/or one of its contractors be a party to a hearing requested by an unrepresented beneficiary. The commenter noted that although § 405.1012(a)(1) expressly precludes CMS or its contractors from electing to be a party when a request for hearing is filed by an unrepresented beneficiary, the phrase “and unless otherwise provided in this section” suggests that an ALJ may request CMS or a contractor to be a party in hearings when the request is filed by an unrepresented beneficiary. The commenter requested that the language in proposed § 405.1012(a)(2) expressly exclude the possibility that an ALJ may request CMS or its contractors to be a party in a hearing when the request for hearing is filed by an unrepresented beneficiary.

*Response:* The “unless otherwise provided in this section” language in proposed § 405.1012(a)(1) was added to address situations in which CMS or a CMS contractor elected to be a party but was precluded from being a party due to limitations on the number of CMS or CMS contractor parties in § 405.1012(d), or due to an election that the ALJ determines is invalid under § 405.1012(e). We agree that when the request for hearing is submitted by an unrepresented beneficiary, CMS and its contractors may not be a party at the hearing. This was our intent in current § 405.1012(a) as well as our intent in proposed § 405.1012(a)(2). Thus, we have revised the language in § 405.1012(a)(2) as finalized in this rule to expressly state that an ALJ may request CMS or one of its contractors to be a party to a hearing unless the request for hearing is filed by an unrepresented beneficiary.

*Comment:* We received one comment from a Recovery Auditor trade/advocacy group that was submitted as a comment to proposed §§ 405.1008 and 423.2008, but was related to how proposed §§ 405.1010, 405.1012 and 423.2010 would impact CMS audit contractors’ interests in hearings and their ability to

elect party status. The commenter noted that audit contractors have both contractual obligations under the draft Statement Work for the Recovery Audit Program to support their findings at hearings and a substantial interest in being permitted to offer a defense of their findings through oral testimony, cross examination, and attendance at the hearings. The commenter recommended that there should be a clear process for deciding which contractor should have primary responsibility for participating in hearings and suggested that the contractor who first denied the claim should be granted party status, with the subsequent contractors taking participant status. As an alternative, the commenter recommended that multiple entities should be permitted to elect to be a party to the hearing, and the ALJ could limit each party to only addressing issues that have not yet been addressed by the other parties. The commenter characterized the rules regarding electing party status in § 405.1012 as a “new process [that] would require frequent requests for leave, if audit contractors are not permitted to act as a party at the ALJ hearing level” and stated that “the requirement that an entity must seek permission from an ALJ to act as a party to a hearing imposes a cumbersome, time-consuming step in the process, increasing the administrative burden on both CMS contractors and on ALJs.” Finally, the commenter noted several concerns regarding timing of the election of party status and delays in audit contractors receiving the notice of hearing. The commenter indicated that the 10-day time limit for electing party status after the QIC receives the notice of hearing is unworkable because QICs frequently do not forward notices of hearings to the audit contractors within 10 calendar days. The commenter recommended that the window to elect party status be expanded to 20 calendar days and/or that QICs should be required to forward all notices of hearings to the audit contractors in a timely fashion, and failure by the QICs to do so should result in an extension in the time that audit contractors have to elect party status. Alternatively, the commenter recommended that ALJs should be required to notify audit contractors of all ALJ hearings directly. The comment noted that if QICs, which may receive the notice of hearing first, preemptively elect party status before the audit contractors receive notice of a hearing, audit contractors would be prevented from participating at the hearing, and such exclusion would

make it difficult for audit contractors to satisfy their contractual obligations and raises due process concerns.

*Response:* We believe that the rules we are finalizing on CMS and contractor participant and party status strike an appropriate balance between administrative efficiency and obtaining as much information as possible for the ALJ to render a decision on the matter. In addition, we believe that §§ 405.1010, 405.1012, and 423.2010, as finalized in this rule, continue to allow for effective participation in the ALJ hearing process for QICs and other contractors consistent with 1869(c)(3)(J) of the Act and current §§ 405.1010 and 405.1012, as further discussed below.

Section 405.1012(d)(1), as finalized in this rule, limits party status at the oral hearing to the first entity to elect party status after the notice of hearing is issued, but any other entity that filed an election for party status is made a participant in the proceedings under proposed § 405.1010 (subject to § 405.1010(d)(1) and (3)), and may file a position paper and/or written testimony to clarify factual or policy issues in the case. We believe that allowing a contractor that is precluded from being a party to the hearing to file positions papers and/or written testimony still provides the contractor with a meaningful opportunity to participate in the proceedings. As we explained in the proposed rule, we considered alternatives to the first to file provision in proposed § 405.1012(d)(1). However, we believe that providing that the first entity to elect party status be made a party to the hearing is an administratively efficient and objective method of determining which contractor will be made a party to the hearing if more than one entity makes a party election. We do not agree with the commenter that the first contractor to deny the claim is necessarily the best entity or the most beneficial entity to have at the hearing. In some cases, subsequent contractors may have resolved the issue identified by the first contractor and further developed the record, and that subsequent contractor may have a more current understanding of the issues on appeal and the facts. In addition, when multiple contractors would be necessary for a full examination of the matters at issue, §§ 405.1010(d)(3) and 405.1012(d)(2) as finalized could be used by the ALJ to grant leave to a precluded entity to participate in the oral hearing or to be a party to the hearing, respectively. Although the commenter suggested that as an alternative, multiple parties should always be permitted to participate at the oral hearing and the

ALJ could use his or her discretion to limit testimony and argument as necessary, we believe that the process finalized in this final rule is more efficient and provides more clarity regarding expectations.

We also disagree with the commenter’s characterization of the process for CMS or its contractor to elect to be a party to the hearing as “new” to the extent that § 405.1012(b), as finalized in this rule, follows the same process in current § 405.1012(b) for electing party status by sending written notice of intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant. Although § 405.1012(d), as finalized in this rule, places a new limitation on the number of contractors who have elected to be a party that may participate in the oral hearing, unless the ALJ grants leave to an entity to also be a party to the hearing, we do not believe this process imposes an additional administrative burden or time-consuming step. Section 405.1012(d)(2) states that if CMS or a contractor is precluded under the rules from being a party to a hearing, an ALJ may grant leave for CMS or a contractor to be a party to the hearing if the ALJ determines that the entity’s participation as a party is necessary for a full examination of the matters at issue. We disagree that this determination by the ALJ imposes any cumbersome, time-consuming, or administratively burdensome requirements on CMS of its contractors. While the commenter has characterized the process as requiring that entities “seek permission from the ALJ to act as a party to the hearing,” we do not agree that § 405.1012(d)(2), as finalized in this rule, necessarily requires any additional filings or actions from the entity other than the written notice of intent to participate as a party provided for in § 405.1012(b).

With respect to the commenter’s concern regarding audit contractors’ ability to meet contractual obligations, including the concern that QICs may preemptively elect party status and preclude participation or party status for audit contractors, we direct the commenter to our response to a similar comment above that was submitted by a QIC. As we noted above, after the final rule is effective, we intend to issue sub-regulatory guidance, including educational materials and contractual modifications that will establish processes to accommodate the regulatory changes and help ensure contractor understanding of roles and responsibilities. These processes will relate to timely notice, information



sharing, and coordination among affected contractors that may have an interest in participating in the same hearing. In addition, we intend to update the Joint Operations Agreements to capture contractor roles and establish timeframes. CMS intends to make any necessary modifications to its contractors' statements of work and contracts to require coordination among the multiple contractors who may have an interest in electing participant and/or party status in the same hearing.

Finally, we recognize that there may be some delay in certain contractors' receipt of the notice of hearing as it is processed through the QICs. However, we believe that the 10 calendar day time frame still provides adequate time to give notice to all contractors. The timeframe for forwarding a notice of hearing is reflected in the QIC contracts. CMS will take steps to help ensure that the QICs and other contractors follow the applicable regulations and contractual requirements. Because the QICs' contractual obligations already reflect a workable timeframe, and because CMS will take steps to help ensure that the QICs follow those contractual obligations, we do not agree that the first two alternatives suggested by the commenter—revising the regulations to extend the time frame to elect party status to 20 days or extending the timeframe to elect party status if a QIC fails to timely notify contractors of the receipt of a notice of hearing—are necessary. We believe that the commenter's third suggestion of requiring that OMHA always send the notice of hearing to all contractors places an unnecessary administrative burden on OMHA and would duplicate the process for notifying the various contractor entities that is already managed by CMS through the QICs' contracts. As we noted above, after the final rule is effective, we intend to issue sub-regulatory guidance that will establish processes to accommodate the regulatory changes. CMS will begin the process of modifying contract provisions with regards to notices of hearing after the effective date of this final rule. In addition, we note that any contractor, including an audit contractor, that has elected to participate in the proceedings on a request for an ALJ hearing under § 405.1010 will receive notice of a hearing, if one is scheduled, directly from OMHA pursuant to § 405.1020(c)(1) as finalized in this rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 405.1010, 405.1012, and 423.2010 as

proposed, with the following modifications. We are adding a requirement in §§ 405.1010(c)(3)(ii), 405.1012(c)(2)(ii) and 423.2010(d)(3)(ii) that copies of position papers and/or written testimony (and for purposes of § 405.1012(c)(2)(ii), any evidence) submitted to OMHA must be sent to the other parties within the same timeframes that apply to the submissions to OMHA. In addition, we are adding language to § 405.1010(d)(3) to state that if the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with § 405.1012. To accommodate this change, we are also revising § 405.1010(c)(2) to state that when CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in § 405.1010(d)(3). We are also adding clarifying language in § 405.1012(a)(2) that an ALJ may not request that CMS and/or one or more of its contractors be a party to the hearing if the request for hearing was filed by an unrepresented beneficiary. Finally, we are correcting a drafting error in the text of proposed § 405.1010(c)(3)(i) by replacing "by within 14 calendar days" with "within 14 calendar days."

g. Request for an ALJ Hearing or Review of a QIC or an IRE Dismissal (§§ 405.1014 and 423.2014)

Sections §§ 405.1014 and 423.2014 explain the requirements for requesting an ALJ hearing, including what must be contained in the request, when and where to file the request, the extension of time to request a hearing, and in § 405.1014 to whom a copy of the request for hearing must be sent. We proposed to restructure the sections, clarify and provide additional instructions, and address other matters that have caused confusion for parties and adjudicators. 81 FR 43790, 43816–43820.

i. Requirements for a Request for Hearing or Review of a QIC or an IRE Dismissal

We proposed to revise the title and provisions of §§ 405.1014 and 423.2014 to more clearly cover a request for a review of a QIC or IRE dismissal. While the current requirements for requesting an ALJ hearing are generally used for requesting a review of a QIC or IRE dismissal in form HHS–725, we stated in the proposed rule that we believe that explicitly extending §§ 405.1014 and

423.2014 to cover requests for these types of review would provide clarity to parties and adjudicators on the requirements for requesting a review of a QIC or IRE dismissal. As such, we proposed in the title to § 405.1014 and in subsection (a)(1) (current subsection (a)) to add "or a review of a QIC dismissal" after "ALJ hearing," and in subsection (c) (current subsection (b)) to delete "after a QIC reconsideration" and add "or request for review of a QIC dismissal" after "an ALJ hearing." Similarly, we proposed in the title to § 423.2014 and in subsection (a)(1) (current subsection (a)) to add "or a review of an IRE dismissal" after "ALJ hearing," and in subsection (d) (current subsection (c)) to add "or request for review of an IRE dismissal" after "IRE reconsideration."

We proposed in § 405.1014(a)(1)(i) through (a)(1)(vi) to incorporate current § 405.1014(a)(1) through (a)(6) with revisions. In addition to the current requirements in subsection (a)(1), we proposed in § 405.1014(a)(1)(i) to require the beneficiary's telephone number if the beneficiary is the filing party and is not represented. We stated in the proposed rule that this would help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We proposed in § 405.1014(a)(1)(ii) to require the appellant's telephone number, along with the appellant's name and address as currently required in subsection (a)(2), when the appellant is not the beneficiary, and in § 405.1014(a)(1)(iii) to require a representative's telephone number, along with the representative's name and address which is currently included in subsection (a)(3), if a representative is involved. Like the beneficiary telephone number requirement, we stated that these requirements would help ensure that OMHA is able to make timely contact with a non-beneficiary appellant and any representative involved in the appeal to clarify the filing or other matters related to the adjudication of the appeal, including scheduling the hearing. Current subsection (a)(4) states that the request must include the document control number assigned to the appeal by the QIC, if any. We proposed in § 405.1014(a)(1)(iv) to require the Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed, to reduce confusion for appellants. We proposed in § 405.1014(a)(1)(v) to add

language to the current language in subsection (a)(5), so that instead of requiring the “dates of service,” we would require the “dates of service for the claims being appealed, if applicable,” because an appellant may appeal some but not all of the partially favorable or unfavorable claims in a QIC reconsideration and a small number of appeals do not involve a date of service (for example, entitlement appeals). We proposed to incorporate the same language in current subsection (a)(6) into proposed subsection (a)(1)(vi).

We proposed to add a new requirement to the content of the request in § 405.1014(a)(1)(vii) by requiring a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. We stated that this information is necessary to assist OMHA staff in checking whether the provider or supplier was excluded from the program on the date of service at issue prior to scheduling a hearing or issuing a decision, as well as for the ALJ to determine whether to request the participation of CMS or any program integrity contractors that may have been involved in reviewing the claims below. However, we noted that the information is only required if the filing party is aware of an investigation and proceeding, and the information would not be the basis for a credibility determination on evidence or testimony, as an investigation or allegations prior to findings of wrongdoing by a court of competent jurisdiction are not an appropriate foundation for credibility determinations in the context of part 405, subpart I administrative appeals.

As discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above, we proposed changes to the methodology for calculating the amount in controversy required for an ALJ hearing to better align the amount in controversy with the actual amount in dispute. We also proposed new § 405.1014(a)(1)(viii) to require that providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim, as specified in § 405.1006(d), unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. As we discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above, we

stated that in instances where the Medicare allowable amount would serve as the basis for the amount in controversy (which we believe would be the majority of Part B appeals), we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS tools and resources to determine the allowable amount used as the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) and arrive at the amount in controversy after deducting any Medicare payments that have already been made or awarded and any deductible and/or coinsurance that may be collected for the items and services in the disputed claim. In addition, we stated that we believe that providers, suppliers, applicable plans, and Medicaid State agencies also would have access to the billing, payment and other necessary information to calculate the amount in controversy under other provisions of § 405.1006(d). For scenarios where the basis for the amount in controversy would be calculated in accordance with proposed § 405.1006(d)(2)(i)(B), (ii), (iii), or where the amount in controversy would be calculated in accordance with § 405.1006(d)(3), (5), (6), or (7), we discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above how appellants would determine the amount in controversy in order to include it on their request for hearing. However, we stated that because we believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not have the information necessary to determine the amount in controversy under § 405.1006(d) (as discussed above), we did not propose to require beneficiaries who are not represented by a provider, supplier, or Medicaid State agency to include the amount in controversy in their requests for hearing. Furthermore, as noted above, we did not propose that any appellant include the amount in controversy on requests for hearing where the amount in controversy would be calculated in accordance with § 405.1006(d)(4) (for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). We stated that we expected in this situation, a beneficiary could easily determine whether the minimum amount in controversy required for an ALJ hearing would be met through a conversation with the provider or supplier, or from the statement we proposed that the QIC

include in its notice of reconsideration as discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above. However, we stated that we believe the exact amount in controversy could be difficult to determine because it may depend on unknown factors, such as the length of continued services that may be required, and so we are not requiring appellants to include this amount in the request for hearing.

Lastly, we proposed that current § 405.1014(a)(7), which requires a statement of any additional evidence to be submitted and the date it will be submitted, would be separately designated in its entirety as proposed § 405.1014(a)(2) because the information in proposed § 405.1014(a)(1) must be present for a request for hearing to be processed and therefore would make the request subject to dismissal if the information is not provided, as discussed below. In contrast, we stated that the information in proposed § 405.1014(a)(2) is only necessary if evidence would be submitted and would not make the request subject to dismissal if not present in the request.

Similar to proposed § 405.1014(a), we proposed at § 423.2014(a)(1)(i) through (a)(1)(vi) to incorporate current § 423.2014(a)(1) through (a)(6) with revisions. Current subsection (a)(3) states that the request must include the appeals case number assigned to the appeal by the IRE, if any. We proposed in § 405.1014(a)(1)(iii) to revise the requirement to state that the request must include the Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed, to reflect the terminology used by the IRE and thereby reduce confusion for enrollees. Current subsection (a)(6) states that the request must include the reasons the enrollee disagrees with the IRE’s reconsideration. We proposed to insert “or dismissal” after “reconsideration” to again reflect the terminology used by the IRE and thereby reduce confusion for enrollees. For the same reasons as we proposed for § 405.1014(a)(1)(vii), we proposed at § 423.2014(a)(1)(vii) to require a statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. In addition, we proposed at § 423.2014(a)(2) to incorporate the current § 423.2014(a)(7) requirement to include a statement of any additional evidence to be submitted and the date it will be submitted, and at § 423.2014(a)(3) to incorporate the current § 423.2014(a)(8) requirement to include a statement that the enrollee is

requesting an expedited hearing, if applicable.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Several commenters objected to the introduction of proposed § 405.1014(a)(1)(vii), stating that it would be unduly burdensome to require appellants to disclose any and all investigations and proceedings by any law enforcement agency, particularly for large providers such as hospital systems where the proceeding or investigation may relate to a different facility or be otherwise unrelated to the claims on appeal. In addition, the commenters indicated that the requirement was unclear with respect to whether a multi-hospital system would be considered subject to, and therefore required to disclose, an investigation of a single hospital within the system. The commenters also stated that it was unclear which individual in the appellant organization must be aware of the investigation or proceeding to trigger the obligation to disclose, for instance, whether an individual in the hospital's claims department would be obligated to report information that was known to the hospital's legal department. Further, the commenters expressed concern that the existence of a pending investigation, which has not yet determined any wrongdoing, has the potential to unfairly prejudice the adjudicator, who should instead be focused on the merits of the specific claims on appeal. In addition, the commenters stated that there could be instances in which an individual is unable to disclose a proceeding pursuant to a court order.

*Response:* While we continue to believe that adjudicators in the claim appeals process should have information related to systemic issues with appellants that may have a bearing on the credibility of evidence or testimony presented to the adjudicator in an individual claim appeal, we believe the commenters have raised valid questions and concerns with proposed § 405.1014(a)(1)(vii) (which would require appellants to disclose pending investigations or proceedings), that we believe require further consideration. Therefore, we are not finalizing proposed §§ 405.1014(a)(1)(vii) or 423.2014(a)(1)(vii) at this time.

*Comment:* Two commenters suggested allowing beneficiaries to furnish an email address instead of, or in addition to, a telephone number on the request for hearing because beneficiaries may not have immediate or consistent access to a telephone.

*Response:* If the filing party is an unrepresented beneficiary, we proposed to require the beneficiary's telephone number to help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We believe that the majority of beneficiaries will be able to provide a telephone number where they can be contacted by OMHA, or receive voicemail messages regarding their appeal. However, if a beneficiary indicates that he or she does not have a telephone number (for example, by writing "none" or "n/a" as his or her telephone number on the request for hearing or request for review of a QIC or IRE dismissal), the request will not be dismissed as incomplete because the beneficiary provided information related to the telephone number, even though an actual telephone number was not provided. To ensure that a beneficiary's personally identifiable information is protected, any electronic communication between OMHA and a beneficiary would need to be conducted via secure email or a secure portal; however, these technologies are not currently available for use by OMHA staff. Consequently, we believe it is reasonable to require a telephone number as the general rule, and address situations in which a beneficiary does not have a telephone number on an individual basis.

*Comment:* Three commenters opposed requiring appellants to provide the amount in controversy on the request for hearing, arguing that it would increase the burden on appellants and it would be difficult for appellants without access to billing information, such as Medicaid State agencies, to calculate the amount in controversy.

*Response:* As discussed in section II.B.3.d above, we are not finalizing our proposal to use the Medicare allowable amount as the basis for the amount in controversy for appeals of claims that are priced based on a published Medicare fee schedule or published contractor-priced amount. Because we will generally be retaining the existing methodology for calculating the amount in controversy under § 405.1006(d), subject to certain revisions and the exceptions in § 405.1006(d)(2) through (6) as finalized, we believe the information necessary to calculate the amount in controversy will be available in the record and ALJs can continue, as they do now, determining whether the amount in controversy was met on the basis of that information. Accordingly, we are not finalizing proposed

§ 405.1014(a)(1)(viii) to require that providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim.

*Comment:* Two commenters suggested that OMHA should be prohibited from dismissing a timely filed request for hearing due to missing information, such as when an appellant provides incorrect dates of service. The commenters also suggested that the request for hearing form should be simplified to avoid deterring appeals by unrepresented beneficiaries. One commenter added that increasing the burden on appellants by requiring additional information in the request for hearing makes it harder for appellants to exercise their rights.

*Response:* We disagree with the commenters' suggestion that requests for hearing should not be dismissed if an appellant does not provide the required information. A complete request, consistent with §§ 405.1014 and 423.2014, provides OMHA with the minimum information necessary to process the request, identify the claims on appeal, and schedule a hearing if necessary, as efficiently as possible. In addition, if any of the required information is not included in a request, the appellant will be given the opportunity to provide the information, as discussed below in section II.B.3.g.iii of this final rule, before the request may be dismissed (see §§ 405.1014(b)(1) and 423.2014(c)(1) as finalized). As further discussed below in section II.B.3.x of this final rule, the proposal clarifying the ability to dismiss a request due to missing information will prevent an appeal from remaining pending indefinitely if an appellant has demonstrated an unwillingness to provide the information necessary to complete the request. In addition, we believe the information required in the regulations for a complete request for hearing or request for review of a QIC or IRE dismissal will not deter appeals by unrepresented beneficiaries or other appellants. We do not believe §§ 405.1014(a) and (b) and 423.2014(a) and (b), as finalized, would create additional burdens as compared to the current rule, except for requiring a telephone number for the beneficiary, appellant, and that party's representative (as discussed above, other proposed information requirements for filing a request are not being made final). Instead, the final regulations clarify the information requirements for requesting a hearing or

review of a QIC or IRE dismissal and the process for resolving missing information, thereby reducing confusion for appellants and, ultimately, reducing the number of requests that are dismissed as incomplete.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 405.1014 and 423.2014 as proposed, with the following exceptions. We are not finalizing proposed §§ 405.1014(a)(1)(vii), (viii), and 423.2014(a)(1)(vii).

ii. Requests for Hearing Involving Statistical Sampling and Extrapolations

We proposed to add new § 405.1014(a)(3) to address appeals in which an appellant raises issues regarding a statistical sampling methodology and/or an extrapolation that was used in making an overpayment determination. We stated in the proposed rule that OMHA has encountered significant issues when an appellant challenges aspects of a statistical sampling methodology and/or the results of extrapolations in separate appeals for each sampled claim involved in the statistical sampling and/or extrapolation. We stated that appeals often need to be reassigned to avoid multiple adjudicators addressing the challenges to the statistical sampling methodology and/or extrapolation, and any applicable adjudication time frames that attach to the individual appeals. Under proposed § 405.1014(a)(3), if an appellant is challenging the statistical sampling methodology and/or extrapolation, the appellant's request for hearing must include the information in proposed § 405.1014(a)(1) and (a)(2) for each sample claim that the appellant wishes to appeal, be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), and assert the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation in the request for hearing. We stated in the proposed rule that we believed it would be appropriate in this situation to allow the appellant's request for hearing to be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), because if the appellant also wishes to challenge the statistical sampling methodology and/or extrapolation, the appellant would wait to file a request for hearing until all of the QIC reconsiderations for the sample units are received, which could be more

than 60 calendar days after the first received QIC reconsideration of one of the sample claims. We also stated that the 60 calendar day period in proposed § 405.1014(a)(3)(ii) would begin on the date the party receives the last reconsideration of a sample claim, regardless of the outcome of the claim in the reconsideration or whether the sample claim is appealed in the request for hearing. We stated we believed proposed § 405.1014(a)(3) would balance the party's rights to request a hearing on individual claims when only the sample claims are appealed, with the needs to holistically address issues related to statistical sampling methodologies and extrapolations when those determinations are also challenged. We did not propose any corresponding changes to § 423.2014 because sampling and extrapolation are not currently used in Part D appeals.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Several commenters supported the proposal to allow appellants to file a single request for hearing that includes all of the sample claims the appellant wishes to appeal when the sample claims were adjudicated in separate reconsiderations and the appellant is also challenging the sampling methodology and/or extrapolation, so that all of the sample claims and related issues are before the same adjudicator. Two of the commenters specifically noted that revising the time frames to allow an appellant to wait to file a request for hearing until the appellant receives the last reconsideration for the sample claims without losing the right to appeal earlier-decided claims will conserve time and resources for both appellants and OMHA.

*Response:* We thank the commenters for their support.

*Comment:* One commenter stated that the requirement to include information for each sample claim in the request for hearing is too vague and does not provide adequate guidance as to what must be provided, potentially resulting in more requests for hearings being dismissed as incomplete. The commenter further stated that it would be difficult to summarize the expert analyses required for statistical sampling challenges in a manner suitable for a request for hearing.

*Response:* With respect to the individual claim information that must be included in a request for hearing, we do not believe that the standard is vague and will result in an increased number of dismissals due to incomplete requests. Under § 405.1014(a)(3)(i) as

finalized in this rule, if an appellant is challenging the statistical sampling methodology and/or extrapolation, the request for hearing must include all of the information in § 405.1014(a)(1) and (a)(2) for each sample claim that the appellant wishes to appeal. This individual claim information is necessary for OMHA to identify the claims on appeal and process the request for hearing. We note that some of the required information may be the same for all of the sample claims, such as the provider or supplier information, or the Medicare appeal number if the claims were all part of the same reconsideration. Because all of the sample claims must be appealed together under § 405.1014(a)(3) as finalized, any redundant information would only need to be provided once for the request for hearing to be considered complete, and would not need to be listed separately for each claim so long as it is apparent from the request that the information provided applies to all of the appealed claims.

Section 405.1014(a)(3)(iii), as finalized, requires an appellant to include in the request for hearing the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation. If an appellant is unable to summarize the reasons he or she disagrees with the statistical sampling methodology and/or extrapolation in a format suitable for a request for hearing, the appellant may choose to attach a position paper or other documentation to the request for hearing to better explain the reasons for the challenge. We also note that the requirement to include the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted does not limit the appellant's ability to provide additional information or arguments during the course of the appeal. The requirement, which is similar to the existing requirement in § 405.1014 to state the reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed, provides the adjudicator with information on the appellant's basis for the appeal and is necessary to evaluate the record and prepare for the hearing. Moreover, a request for hearing may not be dismissed as incomplete based on the strength of the appellant's reasons for disagreeing with the statistical sampling methodology and/or extrapolation; a dismissal for an incomplete request would only result if no reason were provided, and only after an opportunity to cure the request had been provided,

as provided at § 405.1014(b)(1) as finalized.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing § 405.1014(a)(3) as proposed without modification.

### iii. Opportunity To Cure Defective Filings

There has been considerable confusion on the implications of not providing the information required by current § 405.1014(a) in order to perfect a request for hearing, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. To provide clearer standards and reduce confusion, we proposed in § 405.1014(b)(1) that a request for hearing or request for a review of a QIC dismissal must contain the information specified in proposed § 405.1014(a)(1) to the extent the information is applicable, in order to be considered a complete request, and that any applicable adjudication time frame will not begin until the request is complete because the missing information is necessary to the adjudication of the appeal. We proposed in § 405.1014(b)(1) to also provide an appellant with an opportunity to complete any request found to be incomplete. However, we proposed that if the appellant fails to provide the information necessary to complete the request in the time frame provided, the incomplete request would be dismissed in accordance with proposed § 405.1052(a)(7) or (b)(4). In order to reinforce the concept that an appellant's request and supporting materials is considered in its totality, we also proposed at § 405.1014(b)(2) to allow for consideration of supporting materials submitted with a request when determining whether the request is complete, provided the necessary information is clearly identifiable in the materials. For example, we stated in the proposed rule that if an appellant were to submit a request for hearing and included a copy of the QIC reconsideration, the Medicare appeal number on the QIC reconsideration would generally satisfy the subsection (a)(1)(iv) requirement because it clearly provides the required information. However, if there are multiple claims in the QIC reconsideration, the same document possibly would not satisfy subsection (a)(1)(v) because the appellant is not required to appeal all partially favorable or unfavorable claims, and subsection (a)(1)(v) requires the appellant to indicate the dates of service for the claims that are being appealed. Similarly, we stated that

including medical records only for the dates of service that the appellant wishes to appeal would generally not satisfy subsection (a)(1)(v) because it would be unclear whether the appellant intended to limit the appeal to only those dates of service for which medical records were included, or those were the only dates of service for which the appellant had medical records. We proposed that the provisions of proposed § 405.1014(b) also be adopted in proposed § 423.2014(c) for requesting an ALJ hearing or a review of an IRE dismissal in Part D appeals.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter supported the proposal to deem a request complete if supporting materials submitted with the request clearly provide the required information. The commenter encouraged HHS to afford unrepresented beneficiaries as much flexibility and leniency as possible when applying the requirement to submit a complete request for hearing. To that end, the commenter suggested that OMHA should clearly identify any missing information and offer guidance as to where to locate the missing information.

*Response:* As discussed above and in section III.A.3.g.iii of the proposed rule, there has been considerable confusion and considerable time spent on procedural matters concerning the requirements for a request for hearing to be considered complete. We believe that allowing for consideration of supporting materials submitted with a request when determining whether the request is complete, and providing appellants with an opportunity to complete the request if the request is not complete, would provide clearer standards and reduce confusion for all appellants, including unrepresented beneficiaries, with respect to the standards used to determine whether a request is complete. Providing appellants with an opportunity to complete a request for hearing when required information is missing would necessarily involve clearly identifying the missing information for the appellant. Currently, when a request for hearing is missing required information, OMHA sends the appellant a "Request for Hearing Deficiency Notice" that specifies the information that must be provided to complete the request and the time frame in which to respond (generally 60 calendar days). This practice helps ensure that appellants will have an opportunity to provide any missing information before a request is

dismissed as incomplete, and this practice would continue under the final rule.

Allowing for consideration of supporting materials when determining whether a request is complete would also provide ALJs and attorney adjudicators with additional flexibility to deem the request complete, even if all of the information necessary for a complete request is not contained on the same document. We believe the rules as finalized provide all appellants, including unrepresented beneficiaries, with an appropriate level of flexibility in providing that the all documents submitted with a request for hearing will be considered in determining whether a request is complete, and an appropriate level of leniency in providing for an opportunity to supplement the request with any missing information if OMHA identifies missing information that is required for a complete request.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing §§ 405.1014(b) and 423.2014(c) as proposed without modification.

### iv. Where and When To File a Request for Hearing or Review of a QIC or an IRE Dismissal

We proposed to incorporate portions of current § 405.1014(b) in proposed § 405.1014(c) and portions of current § 423.2014(c) in proposed § 423.2014(d) to address when and where to file a request for hearing or review. We proposed in §§ 405.1014(c) introductory language and (c)(1), and 423.2014(d) introductory language and (d)(1), to incorporate a request for a review of a QIC dismissal and a request for a review of an IRE dismissal, respectively, and provide that the current 60 calendar day period to file a request for hearing after a party receives a QIC or an IRE reconsideration also applies after a party receives a QIC or IRE dismissal, which is the time frame stated in §§ 405.1004 and 423.2004 to request a review of a QIC or IRE dismissal, respectively. We also proposed in § 405.1014(c)(1) to add an exception for requests filed in accordance with proposed § 405.1014(a)(3)(ii), because as discussed above, we proposed to require that requests for hearing on sample claims that are part of a statistical sample and/or extrapolation that the appellant also wishes to challenge would be filed together, which may be more than 60 calendar days after the appellant receives the first QIC reconsideration of one of the sample claims. In addition, we proposed to

revise the statement that a request must be “submitted” in current § 423.2014(c)(1), with a request must be “filed” in § 423.2014(d)(1), for consistency with §§ 405.1014 and 422.602, both of which use the term “filed.” We also proposed in §§ 405.1014(c)(2) and 423.2014(d)(2) to replace references to sending requests to the “entity” specified in the QIC’s or IRE’s reconsideration in current §§ 405.1014(b)(2) and 423.2014(c)(2), with sending requests to the “office” specified in the QIC’s or IRE’s reconsideration or dismissal, respectively, so they are properly routed. As discussed in sections III.A.3.b and III.A.3.c of the proposed rule (and discussed in sections II.B.3.b and II.B.3.c above), regarding proposed §§ 405.1002 and 405.1004, and 423.2002 and 423.2004, replacing “entity” with “office” in §§ 405.1014, 423.1972, and 423.2014 would help ensure appellants are aware that a request for hearing or request for a review of a QIC or IRE dismissal must be filed with the office indicated in the QIC’s or IRE’s reconsideration or dismissal and avoid delays. However, we again noted that for the few requests for hearing that are misrouted by a party, a notice would be sent to the appellant when the request for hearing is received in the correct office and the date the timely request was received by the incorrect office would be used to determine the timeliness of the request, in accordance with proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i), which would incorporate the misrouted request provisions from current §§ 405.1014(b)(2) and 423.2014(c)(2)(i). We also proposed in §§ 405.1014(c)(2) and 423.2014(d)(2)(i) that the adjudication time frame is only affected if there is an applicable adjudication time frame for the appeal.

Current § 423.1972(b) states that an enrollee must file a request for a hearing within 60 calendar days of the date of the notice of the IRE reconsideration determination. This requirement differs from § 423.2002(a)(1), which states that a request for hearing must be filed within 60 calendar days after receipt of the IRE’s reconsideration (this is also the standard for filing Part A and Part B requests for hearing after receipt of QIC reconsiderations, at § 405.1002(a)(1)). Thus, we proposed to revise § 423.1972(b)(1) to state that a request for hearing must be filed within 60 calendar days after receipt of the IRE’s reconsideration. We also proposed to add new § 423.1972(b)(2), to incorporate current § 423.2002(d), which provides the date of receipt of the

reconsideration is presumed to be 5 calendar days after the date of the written reconsideration unless there is evidence to the contrary (this is also a presumption for receipt of QIC reconsiderations in Part A and Part B appeals, at § 405.1002). These changes would align proposed § 423.1972(b) with current § 423.2002, and remove potential enrollee confusion on when a request for an ALJ hearing must be filed.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter asked whether the same requirements would apply when a request for hearing is misrouted because the CMS contractor provided the appellant with an incorrect address, for example, if the contractor moved or changed jurisdictions after the address was provided.

*Response:* We assume the requirements to which the commenter is referring are the provisions of current §§ 405.1014(b)(2) and 423.2014(c)(2)(ii), which we proposed to incorporate into proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(ii) as a requirement for OMHA to notify the appellant of the date a misrouted request for hearing is received in the correct office and the commencement of any applicable adjudication time frame. We also stated in the proposed rule that the date a timely request was received by an incorrect office would be used to determine the timeliness of the request (as set forth in proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i)). For most appeals, the notice of reconsideration or dismissal of a request for reconsideration instructs appellants to file their requests for hearing or review of a dismissal with the OMHA central docketing office, and we do not anticipate that changes in CMS contractors or changes to a CMS contractor’s address will affect the accuracy of the filing address that is provided in the QIC’s or IRE’s reconsideration or dismissal. However, for a small segment of cases, such as Part C appeals, the notice of reconsideration instructs appellants to file their requests for hearing or review of a dismissal with the entity that conducted the reconsideration, which then forwards the request, along with the case file, to the OMHA central docketing office. In the event that the entity that conducted the reconsideration changes the address to file a request for hearing or review, due to operational changes or a change in the contractor, there would be a transition plan to address providing a

new address in filing instructions and a process for forwarding requests sent to the previous address. Regardless, if a timely request for hearing or review of a dismissal is mistakenly sent to another CMS contractor, to an incorrect or outdated address, or to an OMHA field office, the request is not treated as untimely or otherwise rejected. In accordance with §§ 405.1014(c)(2) and 423.2014(d)(2)(i) as finalized in this rule, the date the request was received by the incorrect office would be used to determine the timeliness of the request, and OMHA would notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame in accordance with §§ 405.1014(c)(2) and 423.2014(d)(2)(ii) as finalized.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing § 423.1972(b) as proposed without modification. In addition, we are finalizing §§ 405.1014(c) and 423.2014(d) with the following modifications. As discussed in section II.B.3.b above, we are adding language to §§ 405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that a request for an ALJ hearing that is timely filed with an office other than the office specified in the QIC’s or IRE’s reconsideration is not treated as untimely. We are also removing the term “entity office,” which was a drafting error, from proposed § 405.1014(c)(2) and adding “office” in its place.

#### v. Sending Copies of a Request for Hearing and Other Evidence to Other Parties to the Appeal

We proposed to incorporate the portion of current § 405.1014(b)(2) that states that the appellant must also send a copy of the request for hearing to the other parties and failure to do so will toll the ALJ’s 90 calendar day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing in proposed § 405.1014(d) with changes discussed below. Current § 405.1014(b)(2) has been another source of considerable confusion, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. Current § 405.1014(b)(2) requires an appellant to send a copy of the request for hearing to the other parties. Other parties consist of all of the parties specified in § 405.906(b) as parties to the reconsideration, including beneficiaries in overpayment cases that involve multiple beneficiaries who have

no liability, in which case the QIC may elect to only send a notice of reconsideration to the appellant, in accordance with § 405.976(a)(2). We proposed in § 405.1014(d)(1) to amend the current copy requirement by only requiring an appellant to send a copy of a request for an ALJ hearing or review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. We stated in the proposed rule that this change would make the standard consistent with requests for Council review, a copy of which must be sent by the appellant to the other parties who received a copy of an ALJ's decision or dismissal, in accordance with current § 405.1106(a). We also stated that this change would also extend the requirement to requests for review of a QIC dismissal to provide the other parties who received notice of the QIC's dismissal action with notice of the appellant's appeal of that action.

We also proposed in § 405.1014(d)(1) to address whether copies of materials that an appellant submits with a request for hearing or request for review of a QIC dismissal must be sent to other parties. Currently some ALJs consider the materials to be part of the request and require an appellant to send copies of all materials submitted with a request, while other ALJs do not consider the materials to be part of the request. We proposed in § 405.1014(d)(1) that if additional materials submitted with a request are necessary to provide the information required for a complete request in accordance with proposed § 405.1014(b), copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). We also proposed that if additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence). For example, if a complete request includes a position paper or brief that explains the reasons the appellant disagrees with the QIC's reconsideration, in accordance with proposed § 405.1014(a)(1)(v), a copy of the position paper or brief would be sent to the other parties, subject to any authorities that apply to disclosing the personal information of other parties. However, we stated that additional evidence such as medical records, is generally not required for a complete request, and therefore copies would not

have to be sent, but could instead be summarized and provided to the other parties at their request, again subject to any authorities that apply to disclosing the personal information of other parties. We stated that this approach would balance the objectives of ensuring that parties to a claim and an appeal of that claim remain informed of the proceedings that are occurring on the claim, with the burdens on appellants to keep their co-parties so informed. We also noted that in sending a copy of the request for hearing and associated materials, appellants are free to include cover letters to explain the request, but we noted that such letters on their own do not satisfy the copy requirement in its current or proposed form. No corresponding changes were proposed in § 423.2014 because the enrollee is the only party to the appeal.

Current § 405.1014 does not contain standards for what constitutes evidence that a copy of the request for hearing or review, or copy of the evidence or a summary thereof, was sent to the other parties, which has led to confusion and inconsistent practices. Therefore, we proposed in § 405.1014(d)(2) to address this issue by establishing standards that an appellant would follow to satisfy the requirement. We proposed in § 405.1014(d)(2) that evidence that a copy of the request for hearing or review, or a copy of submitted evidence or a summary thereof, was sent includes: (1) Certifications that a copy of the request for hearing or request for review of a QIC dismissal is being sent to the other parties on the standard form for requesting a hearing or review of a QIC dismissal; (2) an indication, such as a copy or "cc" line on a request for hearing or review, that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipients; (3) an affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or (4) a mailing or shipping receipt that identifies the name and address of the recipient and what was sent to the recipient. We stated in the proposed rule that we believed these options would provide an appellant with flexibility to document the copy requirement was satisfied and bring consistency to the process.

Beyond stating that an adjudication time frame is tolled if a party does not satisfy the copy requirement, current § 405.1014 does not address the consequence of not satisfying the requirement, and adjudicators are faced with an appeal being indefinitely tolled because an appellant refuses to comply

with the requirement. OMHA ALJs have addressed this issue by providing appellants with an opportunity to send the required copy of the request for hearing, and by informing the appellant that if the copy is not sent, its request will be dismissed. This allows OMHA ALJs to remove requests that do not satisfy the requirement from their active dockets so time and resources can be focused on appeals of those who comply with the rules. We proposed in § 405.1014(d)(3) that, if the appellant fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of the submitted evidence or a summary thereof, the appellant would be provided with an opportunity to cure the defects by sending the request, materials, and/or evidence or summary thereof described in proposed subsection (d)(1). Further, we proposed in § 405.1014(d)(3) that if an adjudication time frame applies, it does not begin until evidence that the request, materials, and/or evidence or summary thereof were sent is received. We also proposed in § 405.1014(d)(3) that if an appellant does not provide evidence within the time frame provided to demonstrate that the request, materials, and/or evidence or summary thereof were sent to other parties, the appellant's request for hearing or review would be dismissed.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received three comments on the proposal clarifying an appellant's obligation to furnish supporting documentation filed with a request for hearing or review of a QIC dismissal to the other parties, which the commenters opposed on the grounds that it would increase the amount of paperwork involved in filing an appeal. The commenters stated it would be costly and burdensome for appellants to produce and send the extra copies; would cause delays and increased time spent on appeals; and would be confusing for beneficiaries who are otherwise uninvolved in the appeal to receive additional paperwork.

*Response:* We do not agree that this proposal increases the amount of paperwork that an appellant is required to send to the other parties. Proposed § 405.1014(d)(1) incorporates the requirement to send a copy of the request for hearing to the other parties from current § 405.1014(b)(2). As noted above, there has been considerable confusion under the current rule as to whether materials submitted with a request for hearing are considered part of that request and, therefore, whether



copies of that material must be sent to the other parties. Currently some ALJs consider any materials sent with the request for hearing to be part of the request and require an appellant to send copies of all the materials submitted with a request to the other parties. The proposed clarification will standardize how this requirement is applied and bring uniformity to the filing process by limiting the materials that must be sent to the other parties to those materials that provide the information that is required for a complete request in accordance with proposed § 405.1014(b). Any evidence that is not required for a complete request can be simply summarized and provided to the other parties at their request, subject to any authorities that apply to disclosing the personal information of other parties. For example, if new evidence is submitted in the form of medical records, a brief description explaining that medical records were submitted and how to contact the appellant for a copy of those medical records can be provided to the other parties, rather than sending copies of the medical records with the copy of the request for hearing. In contrast, if a copy of the QIC reconsideration is included for the purpose of providing the Medicare appeal number or claim-specific information that is required for a complete request for hearing (that is, the information is not contained on a request for hearing form or letter sent from the appellant requesting the appeal), then a copy of the QIC reconsideration would have to be sent to the other parties because the appellant is relying on it to provide information required for a complete request for hearing.

We further note that § 405.1014(d)(1) as finalized actually reduces the number of recipients to whom an appellant is required to send a copy of the request and other materials. Instead of all of the parties to the reconsideration, which potentially includes beneficiaries who are not liable in overpayment cases that involve multiple beneficiaries, and therefore did not receive the notice of reconsideration in accordance with § 405.976(a)(2), § 405.1014(d)(1) as finalized only requires an appellant to send a copy to those parties who received a copy of the QIC's reconsideration or dismissal. This change will reduce the time and expense for an appellant to produce and send the required copies, and will reduce the amount of paperwork sent to beneficiaries who are otherwise uninvolved in the appeal.

*Comment:* One commenter recommended, as an alternative

approach, only requiring providers to notify the beneficiary of the outcome of an appeal, and only in cases where the claims remain denied.

*Response:* We do not believe that notifying beneficiaries solely of the outcome of the appeal when a claim remains denied would be sufficient in cases where the beneficiary received notice of the QIC's reconsideration or dismissal. Providing a complete copy of the request for hearing or review of a dismissal to the other parties is necessary to ensure that beneficiaries remain informed of the proceedings related to items or services furnished to them and can provide information or make inquiries about the appeal if they wish to do so. However, we also emphasize that, under the final rule, appellants are not required to send a copy of the request for hearing or review of a dismissal to any party that did not receive notice of the QIC's reconsideration or dismissal. This aligns the standard with current § 405.1106(a), which requires appellants to send a copy of a request for Council review to the other parties who received a copy of an ALJ's decision or dismissal.

*Comment:* Another commenter asserted that requiring an appellant to send copies of additional materials sent with a request for hearing or review of dismissal to the beneficiaries would discourage filing requests for claims involving multiple beneficiaries together due to confidentiality issues, and would result in more individual appeals and increased delays.

*Response:* We do not agree that requiring appellants to send the other parties a copy of the complete request, including any additional materials that are necessary to complete the request, will discourage appellants from filing requests for claims involving multiple beneficiaries together. While appellants must comply with any authorities that apply to disclosing the personal information of other parties, if an appeal involves multiple beneficiaries, we believe the minor inconvenience of redacting a party's personal information from a brief or position paper when sending a copy to the other parties will be outweighed by the added efficiency of appealing multiple claims together in one request. We also note that in overpayment appeals that involve multiple beneficiaries who have no liability, the QIC generally does not send a copy of the reconsideration to the beneficiaries in accordance with § 405.976(a)(2), and under § 405.1014(d)(1) as finalized, a copy of the request for hearing or review of a dismissal is only sent to the parties who received a copy of the reconsideration.

In addition, we note that the current requirement to send a copy of the request for hearing to all parties to the QIC reconsideration, regardless of whether the parties were sent a copy of that reconsideration, which has been in place since part 405, subpart I was promulgated in 2005, has not appeared to discourage appellants from filing appeals of QIC reconsiderations individually or together. Thus, for the reasons discussed above, we do not believe that § 405.1014(d) as finalized in this rule will discourage filing requests for hearing for multiple beneficiaries together, or result in more individual appeals or increased delays.

*Comment:* One commenter expressed concern that unrepresented beneficiaries may have difficulty identifying where to send the required copies, determining which materials need to be copied, or summarizing other evidence. The commenter suggested that unrepresented beneficiaries should be afforded leniency or assisted with meeting the copy requirement, and suggested that QIC reconsiderations and dismissals should include the full names and mailing addresses of the parties so that appellants can easily find the information.

*Response:* We thank the commenter for its suggestions. We agree that unrepresented beneficiaries may have difficulty determining where to send copies of a request, or what materials to provide to the other parties. Historically, if it is not apparent that an unrepresented beneficiary sent a copy of his or her request to the other parties, it has been the informal practice of both OMHA and the Council to send notice of the request to the other parties on the beneficiary's behalf. In response to the commenter's concerns, we agree that requests filed by unrepresented beneficiaries should not be subject to dismissal for failing to meet this requirement. Accordingly, we are amending § 405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the consequences of failing to send a copy of the request, materials, and/or evidence or summary thereof to the other parties. We are also amending § 405.1052(a)(7) and (b)(4) to reflect this exemption, as discussed in section II.B.3.x below.

With respect to including the full names and mailing addresses of the parties in a QIC reconsideration or dismissal, we thank the commenter for its suggestion and will share this recommendation with the QICs. However, at this time we do not believe that it would be appropriate to add the parties' contact information as a content requirement for QIC reconsiderations

and dismissals in this final rule. Instead, OMHA will continue its current practice of assisting unrepresented beneficiaries with meeting the copy requirement by mailing copies of the request, materials, and/or evidence or summary thereof to the other parties if it is not apparent that copies were sent by the beneficiary.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals to revise § 405.1014(d) with modification. We are amending § 405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the consequences of failing to send a copy of the request for hearing, any additional materials, and/or a copy of submitted evidence or summary thereof, as described in § 405.1014(d)(1), to the other parties.

vi. Extending Time To File a Request for Hearing or Review of a QIC or an IRE Dismissal

We proposed that the provisions of current §§ 405.1014(c) and 423.2014(d) for extensions of time to file a request for hearing would be incorporated in proposed §§ 405.1014(e) and 423.2014(e) with changes, and would extend to requests for reviews of QIC and IRE dismissals. On occasion, OMHA is asked whether a request for an extension should be filed without a request for hearing, for a determination on the request for extension before the request for hearing is filed. We stated that in those instances, we ask the filer to file both the request for hearing and request for extension at the same time because an independent adjudication of the extension request would be inefficient and any adjudication time frame begins on the date that the ALJ grants the extension request, in accordance with current §§ 405.1014(c)(4) and 423.2014(d)(5). We proposed in §§ 405.1014(e)(2) and 423.2014(e)(3) to require a request for an extension be filed with the request for hearing or request for review of a QIC or IRE dismissal, with the office specified in the notice of reconsideration or dismissal. We stated that the revisions we proposed in §§ 405.1014(e)(2) and 423.2014(e)(3) would also align the provisions with proposed §§ 405.1014(c) and 423.2014(d) by specifying that a request for an extension must be filed with the “office,” rather than the “entity,” specified in the notice of reconsideration. We proposed in §§ 405.1014(e)(3) and 423.2014(e)(4) that an ALJ or attorney adjudicator may find good cause to extend the deadline to file a request for an ALJ hearing or a request for a review of a QIC or IRE

dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC or IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. As we stated in the proposed rule, because only an ALJ may dismiss a request for an ALJ hearing for an untimely filing in accordance with proposed §§ 405.1052 and 423.2052, an attorney adjudicator could not make a determination on a request for an extension that would result in a dismissal of a request for hearing. We also proposed to incorporate current §§ 405.1014(c)(4) and 423.2014(d)(5) into proposed §§ 405.1014(e)(4) and 423.2014(e)(5), but indicate that the adjudication time frame begins on the date the ALJ or attorney adjudicator grants the request to extend the filing deadline only if there is an applicable adjudication period. Finally, we proposed in §§ 405.1014(e)(5) and 423.2014(e)(6) to add a new provision to provide finality for the appellant with regard to a determination to grant an extension of the filing deadline. We proposed that if an ALJ or attorney adjudicator were to make a determination to grant the extension, the determination is not subject to further review. However, we did not propose to preclude review of a determination to deny an extension because such a denial would result in a dismissal for an untimely filing, and the dismissal and determination on the request for an extension would be subject to review by the Council.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing our proposals, as discussed above, without modification to revise §§ 405.1014(e) and 423.2014(e).

h. Time Frames for Deciding an Appeal of a QIC or an IRE Reconsideration or an Escalated Request for a QIC Reconsideration, and Request for Council Review When an ALJ Does Not Issue a Decision Timely (§§ 405.1016, 405.1104 and 423.2016)

i. Section 405.1016: Time Frames for Deciding an Appeal of a QIC Reconsideration or an Escalated Request for a QIC Reconsideration

As discussed below, we proposed changes to § 405.1016, which addresses the adjudication time frames for requests for hearing filed after a QIC has issued its reconsideration, in accordance with section 1869(d)(1)(A) of the Act, and escalations of requests for a QIC reconsideration when the QIC does not issue its reconsideration within its adjudication time frame, which is permitted by section 1869(c)(3)(C)(ii) of the Act. 81 FR 43790, 43820–43821 We proposed to revise the title of § 405.1016 from “Time frames for deciding an appeal before an ALJ” to “Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration” because the section specifically applies to appeals of QIC reconsiderations and escalated requests for QIC reconsiderations (as specified in current and proposed § 405.1016(a) and (c)). This revision would also allow for application of this section to requests for hearing adjudicated by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to replace each instance of the term “the ALJ” with “the ALJ or attorney adjudicator” throughout proposed § 405.1016 to assist appellants in understanding that an adjudication time frame, and the option to escalate, also would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We did not propose to change the reference to “a request for an ALJ hearing” because, as explained in section II.B of the proposed rule and II.A.2 above, even if an appellant waives its right to hearing, the case would remain subject to a potential oral hearing before an ALJ, and we believe the request is therefore properly characterized as a request for an ALJ hearing.

We proposed to add titles to proposed § 405.1016(a) to indicate that this paragraph discusses the adjudication period for appeals of QIC reconsiderations, and proposed § 405.1016(c) to indicate that this

paragraph discusses the adjudication period for escalated requests for QIC reconsiderations. In addition, we proposed at § 405.1016(a) and (c) to remove “must,” in providing that when a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC’s notice of reconsideration. While the statute envisions that appeals will be adjudicated within the statutory time frame, the statute also provides for instances in which the adjudication time frame is not met by allowing an appellant to escalate his or her appeal to the next level of appeal. We believe “must” should be reserved for absolute requirements, and in the context of adjudication time frames, the statute provides the option for an appellant to escalate an appeal if the adjudication time frame is not met.

We proposed to add a title to proposed § 405.1016(b) to indicate that the paragraph discusses when an adjudication period begins. We also proposed to re-designate current § 405.1016(b), which explains that the adjudication period for an appeal of a QIC reconsideration begins on the date that a timely filed request for hearing is received unless otherwise specified in the subpart, as § 405.1016(b)(1). We proposed in § 405.1016(b)(2) that if the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c), the remanded appeal would be subject to the adjudication time frame of § 405.1016(a) beginning on the date that OMHA receives the Council remand. Currently the regulations do not address whether an adjudication time frame applies to appeals that are remanded from the Council, and whether escalation is an option for these appeals. To provide appellants with an adjudication time frame for remanded appeals that were subject to an adjudication time frame when they were originally appealed to OMHA, we proposed in § 405.1016(b)(2) to apply the adjudication time frame under § 405.1016(a) to a remanded appeal that was subject to an adjudication time frame under paragraph (a) or (c). For example, if an ALJ decision reviewed by the Council involved a QIC reconsideration and was remanded by the Council, a 90 calendar day time frame would apply from the date that OMHA received the remand order. If the

adjudication time frame is not met under proposed § 405.1016(b)(2), the appeal would be subject to escalation, in accordance with proposed § 405.1016(e).

In addition, we proposed in § 405.1016(a) and (b) to align the paragraphs with proposed § 405.1014(c) by specifying that a request for hearing is received by the “office,” rather than the “entity,” specified in the QIC’s notice of reconsideration.

We proposed to add a title to proposed § 405.1016(d) to indicate that the paragraph discusses waivers and extensions of the adjudication period. We proposed in § 405.1016(d)(1) to incorporate the adjudication period waiver provision in current § 405.1036(d), which states that, at any time during the hearing process, the appellant may waive the adjudication deadline specified in § 405.1016 for issuing a hearing decision, and that the waiver may be for a specific period of time agreed upon by the ALJ and the appellant. We proposed to move the provision because, as we stated in the proposed rule, we believe it is more appropriately addressed in § 405.1016, as it is directly related to the adjudication period. We also proposed in § 405.1016(d) to revise the language in current § 405.1036(d) to reference an attorney adjudicator consistent with our proposals in section II.B of the proposed rule and as discussed in section II.A.2 above; to reference the “adjudication” process rather than the “hearing process” to account for appeals that may not involve a hearing; to consistently reference an adjudication “period” for internal consistency; and to replace the reference to § 405.1016 with internal paragraph references.

Current § 405.1016 does not address delays that result from stays ordered by U.S. Courts. In addition, we have had instances in which an appellant requests a stay of action on his or her appeals while related matters are addressed by another court or tribunal, or by investigators. To address these circumstances, we proposed in § 405.1016(d)(2) that the adjudication periods specified in paragraphs (a) and (c) are extended as otherwise specified in subpart I, and for the duration of any stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction, or the duration of any stay of proceedings granted by an ALJ or attorney adjudicator on the motion of the appellant, provided no other party also filed a request for hearing on the same claim at issue.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received fifteen comments opposing our proposal to remove “must” from § 405.1016(a) and (c). Commenters opposed the proposal on the grounds that the 90-day adjudication time frame is a statutory requirement under section 1869 of the Act, and removing “must” undermines the duty owed to appellants by OMHA adjudicators and would only serve to increase delays in the appeals process. Several commenters cited a recent decision by the Court of Appeals for the District of Columbia Circuit that held that the statute mandated a decision within ninety days. The commenters stated that the ability to escalate an appeal to the Council is a remedy for when the statutory deadline is not met, as opposed to an alternative to the timely adjudication of an appeal, and the existence of that remedy does not negate the mandatory nature of the statutory time frame. One commenter opposed the proposal with respect to appeals filed by beneficiaries and Medicaid State agencies, asserting that escalation is an inadequate remedy for those appellants because it means forgoing a level of administrative review where beneficiaries have historically had the greatest likelihood of success, and facing similar delays at the Council. Another commenter stated that it was particularly important not to weaken the statutory right to a timely decision for low-income beneficiaries. One commenter interpreted the proposal as eliminating the option to escalate an appeal if the adjudication time limit is exceeded.

*Response:* We do not agree that removing “must” from § 405.1016(a) and (c) would undermine or weaken the adjudication time frame set forth in section 1869(d)(1)(A) of the Act. We recognize that one court of appeals has held that the statutory timeframe is mandatory, while another court of appeals has not. Compare *Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016) (holding that the Act does not provide a clear and indisputable right to adjudication of appeals before an ALJ within 90 days) with *American Hospital Association, et al. v. Burwell*, 812 F.3d 183, 192 (D.C. Cir. 2016) (holding that the Act imposes a clear duty on the Secretary to comply with the statutory time frame). We respectfully disagree that the statute mandates that all ALJ decisions reviewing QIC reconsiderations be issued within 90 days. Section 1869(d)(3)(A) of the Act,

which provides for the consequences of failing to meet the adjudication time frame to render a decision in an appeal of QIC reconsideration decision made under section 1869(c) of the Act, contemplates that the adjudication time frame for an ALJ to render such a decision will not always be met, and provides the option for an appellant to request a review by the Council if the ALJ adjudication time frame is not met. Consistent with this section, § 405.1016(f), as finalized in this rule, provides for escalating an appeal of a QIC reconsideration to the Council when a decision, dismissal, or remand is not issued by an ALJ or attorney adjudicator within the adjudication time frame. Removing “must” does not abrogate the general expectation that a decision, dismissal, or remand will be issued within an applicable adjudication time frame, such as the 90 day time frame provided for at section 1869(d)(1)(A) of the Act to render a decision in an appeal of QIC reconsideration decision made under section 1869(c) of the Act. As we conveyed in the proposed rule, removing “must” only has the effect of more appropriately setting expectations with regard to whether there is an absolute and unqualified requirement to issue a decision, dismissal, or remand within the adjudication time frame. Removing the word “must” from § 405.1016(a) and (c) also does not change the amount of time that an ALJ or attorney adjudicator has to issue a decision, dismissal, or remand before an appellant may choose to escalate his or her appeal to the Council. Moreover, removing “must” will have no effect on ALJs (and attorney adjudicators) issuing a decision, dismissal, or remand as quickly as possible, thus the change will not result in increased delays in obtaining a decision, dismissal, or remand. The Department has publicly committed itself to resolving the appeals backlog as quickly as possible while acting within statutory constraints. In particular, appeals brought by beneficiaries are prioritized under current OMHA policy and are generally decided within the applicable adjudication time frame.

*Comment:* One commenter pointed out that we did not propose to remove “must” from other sections of the regulations where it appears, such as current § 405.1014(b)(1), which states that a request for an ALJ hearing after a QIC reconsideration must be filed within 60 days from the date the party receives notice of the reconsideration. Two commenters stated that if filing deadlines and other regulatory time

frames are mandatory for the parties, they should be mandatory for the government, too.

*Response:* Although we recognize that there are other uses of “must” in the regulations that we did not propose to revise, those are distinguishable. As we stated in the proposed rule, we believe “must” should be reserved for absolute requirements. In those instances, the result of not meeting the requirement does not trigger another option. As the commenter identified, current § 405.1014(b)(1) provides that a request for hearing after a QIC reconsideration must be filed within 60 calendar days from the date the party receives notice of the reconsideration. However, we also note that current § 405.1014(c) provides for extensions of that time frame in certain circumstances. Current § 405.1014(b)(1) implements section 1869(b)(1)(D)(ii) of the Act, which provides that “[t]he Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 205 and 206” of the Act. Section 205(b)(1) of the Act in turn provides that a request for hearing “must be filed within [60] days after notice of [the decision being appealed] is received by the individual making such request.” Thus the statute establishes a clear duty for the appealing party to request a hearing within a specific time period after receiving a decision that the party wishes to appeal. If the party does not act, the party does not have a right to a hearing. However, we again note that when the time limit for filing a request for hearing is not met, the Secretary provides a mechanism for a party to request an extension for good cause in current § 405.1014(c).

In contrast to the time limit for filing a request for hearing, § 405.1016(a) and (c) set forth time frames to obtain a decision, dismissal, or remand, which, consistent with section 1869(d)(3)(A) of the Act, if not met results in the appellant having the option to escalate the appeal to the Council. Whereas the consequence of not meeting the time limit for filing a request for hearing is that an adjudicator is precluded from reviewing the decision being appealed, the consequence of exceeding the adjudication time frames is the appellant then has the option to escalate the appeal to the next level. If the appellant at the hearing level chooses not to escalate his or her appeal to the Council, the appeal remains pending with OMHA in accordance with § 405.1016(e) as finalized, which replaces current § 405.1104(c) explaining the same.

*Comment:* One commenter stated that a decision should be issued in the provider’s favor if the 90-day time frame cannot be met. Another commenter stated that if the government cannot meet its deadlines, the claim should be forfeited.

*Response:* We interpret the commenters’ statements as suggesting that Medicare should pay every denied claim that is the subject of an appeal of a QIC reconsideration for an ALJ hearing if a decision, dismissal, or remand is not issued within the adjudication time frame applicable to the appeal, which could include time in addition to the 90 days based on certain regulatory provisions that allow for the extension of that time for certain actions or events (for example, § 405.1016(d)). We believe such a provision would be inappropriate because Medicare may only pay a claim if the item or service is a covered benefit and coverage is not excluded by statute, and any applicable conditions of payment are met, unless specific statutory criteria are met for limiting liability on denied claims under section 1879 of the Act or waiving an overpayment under section 1870 of the Act. Medicare cannot make payment on a claim when a QIC has issued a reconsideration that determined that the item or service is not covered by Medicare or payment may not be made, and if applicable, that the provisions for limiting liability or waiving an overpayment are not met. Further, there is no statutory limitation on liability or overpayment waiver provision that permits payment to be made if an adjudication time frame is not met. Rather, the statute provides that when an ALJ’s adjudication time frame is not met for an appeal of a QIC reconsideration, the appellant has the option to request a review by the DAB, which is implemented in § 405.1016(f), as finalized in this rule, which provides for escalating an appeal of a QIC reconsideration to the Council when a decision, dismissal, or remand is not issued by an ALJ or attorney adjudicator within the adjudication time frame. Moreover, we believe requiring payment to be made on a claim only because an adjudication time frame for an appeal of a denial is not met could increase the appeals workload and raise significant program integrity risks by creating an incentive for providers and suppliers to overwhelm the appeals process with appeals in an effort to obtain payment on claims that may not meet coverage requirements or conditions of payment.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to

§ 405.1016 as proposed without modification.

ii. Incorporation of the Provisions of Section 405.1104 (Request for Council Review When an ALJ Does Not Issue a Decision Timely) Into Section 405.1016(f)

Section 405.1104 addresses how to request escalation from an ALJ to the Council, when an ALJ has not issued a decision, dismissal or remand on a QIC reconsideration within an applicable adjudication time frame, in accordance with section 1869(d)(3)(A) of the Act in paragraph (a); the procedures for escalating an appeal in paragraph (b); and the status of an appeal for which the adjudication time frame has expired but the appellant has not requested escalation in paragraph (c). We proposed to remove and reserve § 405.1104 and incorporate the current § 405.1104 providing for escalating a request for an ALJ hearing to the Council into proposed § 405.1016(e) and (f) with revisions, as its current placement in the Council portion of part 405, subpart I has caused confusion. We also proposed to insert “or attorney adjudicator” after “ALJ” in proposed § 405.1016(e) and (f) to assist appellants in understanding that the effect of exceeding the adjudication period and the option to escalate would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B of the proposed rule and II.A.2 above.

Section 405.1104(c) is titled “No escalation” and states that if the ALJ’s adjudication period set forth in § 405.1016 expires, the case remains pending with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the Council. We proposed in § 405.1016(e) to incorporate § 405.1104(c) with changes. We proposed to revise the paragraph title for proposed § 405.1016(e) to indicate that the paragraph discusses the effect of exceeding the adjudication period. Proposed § 405.1016(e) would provide that if an ALJ or an attorney adjudicator assigned to a request for hearing (as proposed in section II.B of the proposed rule and discussed in section II.A.2 of this final rule above) does not issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in the section, the party that filed the request for hearing may escalate the appeal when the adjudication period expires. However, if the adjudication period expires and the party that filed the request for hearing does not exercise the option to escalate

the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand. We proposed to indicate that the appeal remains pending with OMHA to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned.

Section 405.1104(a) describes how to request an escalation and states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period may request Council review if the appellant files a written request with the ALJ to escalate the appeal to the Council after the adjudication period has expired, and the ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016. We proposed in § 405.1016(f)(1) to remove the requirement to request Council review in the course of requesting an escalation and to describe when and how to request escalation. Specifically, we proposed to revise the current procedures at § 405.1104(a) and (a)(1), to provide that an appellant who files a timely request for a hearing with OMHA and whose appeal continues to be pending at the end of an applicable adjudication period may exercise the option to escalate the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council, which would simplify the process for appellants and adjudicators by only requiring appellants to file a single request for escalation with OMHA. We proposed to replace the reference to an appeal that “continues to be pending before the ALJ” in § 405.1104(a) with an appeal that “continues to be pending with OMHA” in proposed § 405.1016(f)(1) to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned. We also proposed that a written request to escalate an appeal to the Council would be filed with OMHA to allow OMHA to provide a central filing option for escalation requests. Section 405.1106(b) requires that the appellant send a copy of the escalation request to the other parties and failing to do so tolls the Council’s adjudication deadline set forth in § 405.1100 until the other parties to the hearing have received notice. As discussed in section III.A.5.c of the proposed rule and II.B.5.c of this final rule below, we proposed to revise

§ 405.1106(b) to require that the request for escalation be sent to other parties who were sent a copy of the QIC reconsideration. Therefore, we also proposed at § 405.1016(f)(1) that the appellant would send a copy of the escalation request to the other parties who were sent a copy of the QIC reconsideration so appellants would be aware of the requirement and which parties must be sent a copy of the escalation request.

Section 405.1104(b) describes the escalation process and states if the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set for in paragraph (a)(2) of the section (later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016), he or she sends notice to the appellant acknowledging receipt of the request for escalation and confirming that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory time frame. Section 405.1104(b)(3) states that if the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of the section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to Council review consistent with § 405.1102(a). We stated in the proposed rule that this process has caused confusion for both appellants and adjudicators because an initial escalation request must be filed with the ALJ, and if the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request or within 5 calendar days from the end of the applicable adjudication period, the appellant must file a request with the Council to move the appeal to the Council level. We also stated that some appellants neglect to take this second step of filing an escalation request with the Council. This leaves it unclear to the ALJ and support staff whether to continue adjudicating the appeal after issuing a notice that the ALJ is unable to issue a decision, dismissal or remand within the later of 5 calendar days of receiving the escalation request or 5 calendar days from the end of the applicable adjudication period. We proposed in § 405.1016(f)(2) to revise the escalation process. Specifically, we proposed that if an escalation request meets the requirements of proposed § 405.1016(f)(1), and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand within the later of 5 calendar days of receiving the request for escalation or 5

calendar days from the end of the applicable adjudication period, OMHA (to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned) would send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of § 405.1016. We also proposed that the notice would state that the QIC reconsideration would be the decision that is subject to Council review consistent with § 405.1102(a); and the appeal would then be automatically escalated to the Council in accordance with § 405.1108. We proposed that OMHA would then forward the case file, which would include the file received from the QIC and the request for escalation and all other materials filed with OMHA, to the Council. We stated in the proposed rule that we believed that this proposed process would help alleviate the current confusion, and would simplify the escalation process for appellants because appellants would not have to file a separate request for Council review after filing an escalation request with OMHA.

Currently, invalid escalation requests are not addressed in the regulations. We proposed in § 405.1016(f)(3) to address invalid escalation requests. We proposed that if an ALJ or attorney adjudicator determines an escalation request does not meet the requirements of proposed § 405.1016(f)(1), OMHA would send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation. For example, we stated in the proposed rule that an escalation request would be deemed invalid if escalation is not available for the appeal, such as appeals of SSA reconsiderations; the escalation request is premature because the adjudication period has not expired; or the party that filed the escalation request did not file the request for hearing. We stated in the proposed rule that if an ALJ or attorney adjudicator were to determine the request for escalation was invalid for a reason that could be corrected (for example, if the request was premature), the appellant could file a new escalation request when the adjudication period expires.

We received no comments on our proposals to revise and incorporate the provisions of § 405.1104 into § 405.1016(e) and (f), other than: (1) Comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney

adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the proposals without modification.

### iii. Section 423.2016: Time Frames for Deciding an Appeal of an IRE Reconsideration

As discussed below, we proposed changes to § 423.2016, which addresses the adjudication time frames for requests for hearing filed after an IRE has issued its reconsideration. 81 FR 43790, 43823. The title of current § 423.2016 states, “Timeframes for deciding an Appeal before an ALJ.” We proposed to revise the title of § 423.2016 to read “Time frames for deciding an appeal of an IRE reconsideration” in order to state that the section addresses adjudication time frames related to appeals of IRE reconsiderations and to accommodate the application of this section to attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and as discussed earlier. We also proposed to insert “or attorney adjudicator” after “ALJ” throughout proposed § 423.2016 so that an adjudication time frame would apply to a request for an ALJ hearing following an IRE reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B of the proposed rule and II.A.2 above.

Current § 423.2016(a) and (b) explain the adjudication time frames for standard and expedited appeals of IRE reconsiderations, respectively. However, the current paragraph titles refer to hearings and expedited hearings. We proposed at § 423.2016(a) and (b) to retitle the paragraphs to refer to standard appeals and expedited appeals because the time frames apply to issuing a decision, dismissal, or remand, and are not limited to appeals in which a hearing is conducted. We proposed at § 423.2016(a) and (b) to remove “must” in providing when an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the IRE, as appropriate, after the request for hearing

is received by the office specified in the IRE’s notice of reconsideration because there may be instances in which a decision, dismissal, or remand cannot be issued within the adjudication time frame, though we stated that we expect those instances to be rare because beneficiary and enrollee appeals are generally prioritized by OMHA. In addition, we proposed in § 423.2016(a) and (b) to replace references to sending a request to the “entity” specified in the IRE’s reconsideration, with the “office” specified in the IRE’s reconsideration notice, to minimize confusion and delays in filing requests with OMHA. Similar to proposed § 405.1016(b)(2), we proposed at § 423.2016(a)(3) and (b)(6) to adopt adjudication time frames for appeals that are remanded by the Council. Specifically, we proposed in § 423.2016(a)(3) that if the Council remands a case and the case was subject to an adjudication time frame, the remanded appeal would be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand to provide enrollees with an adjudication time frame for remanded appeals. In § 423.2016(b)(6), we proposed to require that if the standards for an expedited appeal continue to be met after the appeal is remanded from the Council, the 10-day expedited time frame would apply to an appeal remanded by the Council. If the standards for an expedited appeal are no longer met, the adjudication time frame for standard appeals would apply because the criteria for an expedited hearing are no longer present. Finally, we proposed at § 423.2016(b) to revise the expedited appeal request process to permit an ALJ or attorney adjudicator to review a request for an expedited hearing, but not require the same ALJ or attorney adjudicator to adjudicate the expedited appeal, to provide OMHA with greater flexibility to review and assign requests for expedited hearings, and help ensure the 10-day adjudication process is completed as quickly as the enrollee’s health requires. For example, if an attorney adjudicator were to review a request for an expedited hearing and determine that the standards for an expedited hearing were met, but did not believe a decision could be issued without a hearing, the attorney adjudicator could provide the enrollee with notice that the appeal would be expedited and transfer the appeal to an ALJ for an expedited hearing and decision.

As described in section III.A.3.q of the proposed rule and II.B.3.q below, we proposed to move the provision for

waiving the adjudication period from current § 423.2036(d) to proposed § 423.2016(c) because proposed § 423.2016 addresses adjudication time frames and, as we stated in the proposed rule, we believed the section is a better place for discussing adjudication time frame waivers.

We proposed that the provisions of proposed § 405.1016(d) also be adopted in proposed § 423.2016(c) for adjudication period waivers and stays of the proceedings ordered by a court or granted by an ALJ or attorney adjudicator on motion by an enrollee.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* Two commenters opposed the proposal to remove “must” from § 423.2016(a) and (b), stating that it would be detrimental to beneficiaries given the current state of the appeals system. One commenter added that if beneficiary and enrollee appeals are prioritized by OMHA, there is no compelling reason to alter the time frame requirement.

*Response:* We disagree that the proposal will be detrimental to beneficiaries. As discussed in section II.B.3.h.i above in response to similar comments about our proposal to remove “must” from § 405.1016(a) and (c), removing “must” does not alter the applicable adjudication time frames, and so does not abrogate the general expectation that a decision, dismissal, or remand will be issued within those time frames. Nor will removing “must” have an effect on ALJs and attorney adjudicators issuing a decision, dismissal, or remand as quickly as possible, so the change will not result in delays in obtaining a decision, dismissal, or remand. Moreover, appeals brought by beneficiaries, including appeals by Part D enrollees, are prioritized under current OMHA policy and are generally decided within the applicable adjudication time frame.

We also disagree that the proposal is unnecessary. As we explained in the proposed rule, there may be times in which it is not possible to issue a decision, dismissal, or remand within the applicable adjudication time frame. 81 FR 43790, 43823. Removing “must” from § 423.2016(a) and (b) more accurately reflects that the time frames in those sections will not always be met.

*Comment:* One commenter supported the proposal to adopt adjudication time frames for appeals that are remanded by the Council. The commenter requested clarification regarding how an appellant will know when OMHA receives a remand, starting the adjudication time

frame for cases that are subject to an adjudication time frame.

*Response:* We thank the commenter for its support. We note that when the Council remands an appeal to OMHA, notice of the remand is also sent to the appellant and other parties consistent with § 405.1128. This notice shows the date that a remand was issued by the Council, giving the appellant a general idea of when a remand would have been received by OMHA. If an appellant would like to know the exact date that a remand was received by OMHA for purposes of calculating any applicable adjudication time frame, the appellant can contact OMHA directly or check the status of a specific appeal using AASIS, which provides public access to appeal status information and can be accessed through the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)). Currently, for appeals that have been remanded by the Council, the original ALJ appeal number assigned to the case will display in AASIS with a status indicator of “Reopened,” along with the new ALJ appeal number assigned to the remanded appeal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 423.2016 as proposed without modification.

#### i. Submitting Evidence (§§ 405.1018 and 423.2018)

As described below, we proposed a number of changes to current §§ 405.1018 and 423.2018, which address submitting evidence before an ALJ hearing is conducted. 81 FR 43790, 43823–43824. We proposed to retitle the sections from “Submitting evidence before the ALJ hearing” to “Submitting evidence” because evidence may be submitted and considered in appeals for which no hearing is conducted by an ALJ, and we believe an attorney adjudicator should be able to consider submitted evidence in deciding appeals as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). For the same reason, we proposed in § 423.2018 to replace the references to “hearings” in the heading to paragraph (a) and in the introductory text to paragraphs (b) and (c), with “appeals.” We also proposed to add headings to paragraphs that do not currently have headings, for clarity of the matters addressed in the paragraphs.

Current § 405.1018(a) states that, except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 calendar days of receiving the

notice of hearing). We proposed in § 405.1018(a) to provide for the submission of other evidence, in addition to written evidence, that the parties wish to have considered. Other evidence could be images or data submitted on electronic media. We proposed to also adopt this revision in § 405.1018(b) and § 423.2018(a), (b), and (c). We also proposed in § 405.1018(a) to remove “at the hearing” so that parties would submit all written or other evidence they wish to have considered, and consideration of the evidence would not be limited to the hearing. We proposed a corresponding change to § 423.2018(a).

Current § 405.1018(a) states that evidence must be submitted with the request for hearing, or within 10 calendar days of receiving the notice of hearing. This provision has caused confusion as to when evidence is required to have been submitted because current § 405.1014(a)(7) allows an appellant to state in the request for hearing that additional evidence will be submitted and the date it will be submitted. To reconcile the provisions, we proposed in § 405.1018(a) to provide that parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with proposed § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. We proposed to also adopt these revisions in § 423.2018(b) and (c).

Current § 405.1018(b) addresses how the submission of evidence impacts the adjudication period, and provides that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, the period between when the evidence “was required to have been submitted” and the time it is received does not count towards an adjudication period. To simplify the provision, we proposed at § 405.1018(b) that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received. We also proposed to adopt this provision in § 423.2018(b)(2) and (c)(2), except that in (c)(2), the adjudication time frame is affected if the evidence is submitted later than 2 calendar days after receipt of the notice of expedited hearing because 2 calendar days is the equivalent time frame to submit evidence for expedited appeals before the adjudication period is affected under current § 423.2018.



Current § 405.1018(c) addresses new evidence, and is part of the implementation of section 1869(b)(3) of the Act, which precludes a provider or supplier from introducing evidence after the QIC reconsideration unless there is good cause that prevented the evidence from being introduced at or before the QIC's reconsideration. These provisions, which provide for the early submission of evidence, help adjudicators to obtain evidence necessary to reach the correct decision as early in the appeals process as possible. We proposed to incorporate current § 405.1018(c), which requires a provider, supplier, or beneficiary represented by a provider or supplier that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker, in proposed § 405.1018(c)(1). However, current § 405.1018 does not address the consequences of not submitting the statement. The statute sets a bar to introducing new evidence, and the submitting party must establish good cause by explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. However, when a provider or supplier, or beneficiary represented by a provider or supplier, fails to include the required statement, OMHA ALJs and staff spend time seeking out the explanation and following up with parties to fulfill their obligation. Thus, we proposed to revise § 405.1018(c)(2) to state that if the provider or supplier, or beneficiary represented by a provider or supplier fails to include the statement explaining why the evidence was not previously submitted, the evidence will not be considered. Because only the enrollee is a party to a Part D appeal, we did not propose a corresponding revision to § 423.2018.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter questioned whether directing parties to submit all evidence with the request for hearing is incompatible with the appeal instructions currently sent by QICs, which instruct appellants not to attach evidence to the hearing request and instead submit the evidence directly to the ALJ when the case is assigned.

*Response:* We do not agree that proposed § 405.1018(a) requires an appellant to submit all evidence with the request for hearing, or that the proposals are incompatible with appeal instructions currently sent by QICs. Under current § 405.1018(a), appellants may submit evidence with the request for hearing or within 10 calendar days

of receiving the notice of hearing. However, current § 405.1014(a)(7) also provides that in a request for hearing, an appellant could provide a statement of any additional evidence to be submitted and the date it will be submitted. Due to the significant increase in appeals to OMHA in recent years, OMHA requested that the QICs include language encouraging appellants to use current § 405.1014(a)(7) to submit evidence directly to the ALJ after the appeal was assigned, to help OMHA process requests for hearing more efficiently.

Under proposed § 405.1018(a), we proposed to add an explicit reference to the § 405.1014(a)(7) provision (re-designated as proposed § 405.1014(a)(2)) to more fully specify in proposed § 405.1018(a) when evidence may be submitted. Under proposed § 405.1018(a), evidence can be submitted after a request for hearing is submitted and, therefore, an appellant would not be precluded from submitting the evidence at a later time. For example, an appellant could indicate in the request for hearing that it has additional evidence to submit and will submit it when the appeal is assigned to an adjudicator. However, there may be times when the appellant wishes to submit new evidence with the request for hearing, such as when the appellant waives his or her right to appear at a hearing before an ALJ and requests that a decision be made on the record, or the appellant believes the evidence addresses the issues identified in the reconsideration and including the evidence may increase the likelihood that a decision that is fully favorable could be issued based on the record alone in accordance with proposed § 405.1038(a). The current appeal instructions do not preclude an appellant from submitting evidence with the request for hearing, but rather request that appellants consider submitting it at a later time. Therefore, we believe that by allowing for the submission of evidence with the request for hearing or after the request is submitted, by the date specified in the request for hearing in accordance with § 405.1014(a)(2) or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing, proposed § 405.1018(a) is not incompatible with appeal instructions currently sent by QICs. However, we will review the appeal instructions being issued by QICs to determine if clarification may be appropriate to reduce potential confusion.

*Comment:* Two commenters recommended adding language to specifically state that Medicaid State

agencies are exempt from the requirement of current § 405.1018(c) to provide a statement of good cause explaining why evidence was submitted for the first time at the OMHA level.

*Response:* As discussed above, current § 405.1018(c) is part of the implementation of section 1869(b)(3) of the Act (42 U.S.C. 1395ff(b)(3)), which precludes a provider or supplier from introducing evidence after the QIC reconsideration without a showing of good cause. Considering the language of the statute, which expressly states that this limitation applies to providers and suppliers, we agree that the requirement under § 405.1018(c) to support the introduction of new evidence with a statement of good cause does not apply to Medicaid State agencies. Further, we note that the provision would not apply to other parties or potential parties such as unrepresented beneficiaries, applicable plans, CMS and its contractors, or beneficiaries represented by someone other than a provider or supplier. To address the comment and more broadly clarify the application of the requirements under proposed § 405.1018, we are redesignating proposed § 405.1018(d) as (d)(1) and clarifying that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing, or to evidence submitted by unrepresented beneficiaries, as is the case under current § 405.1018(d). Because current § 405.1018(c) applies only to providers, suppliers, and beneficiaries represented by a provider or supplier, we are also adding paragraph (d)(2) to clarify that the requirements in paragraph (c) to show good cause for the submission of new evidence do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, Medicaid State agencies, applicable plans, CMS and its contractors, or beneficiaries represented by someone other than a provider or supplier.

*Comment:* One commenter stated that any limitation on new evidence prevents a fair hearing because OMHA does not always receive evidence that was submitted earlier in the appeal process. Another commenter suggested that § 405.1018(c)(2) should be amended to provide flexibility for an ALJ or attorney adjudicator to review evidence that was not timely submitted, in his or her discretion, even without an explanation of good cause.

*Response:* We disagree with the commenter that any limitation on new evidence prevents a fair hearing because OMHA does not always receive evidence that was submitted earlier in the appeal process. There are ample

opportunities to submit evidence at the redetermination and reconsideration levels of appeal, and section 1869(b)(3) of the Act expressly states that providers and suppliers may not introduce new evidence in any appeal that was not presented at the reconsideration, unless there is good cause which precluded the introduction of such evidence at or before the reconsideration. This statutory provision was added to promote an efficient appeals process in which adjudicators receive evidence as early in the appeals process as possible, but also allow new evidence to be introduced after the reconsideration when there is good cause. OMHA receives evidence from the contractors and, in the vast majority of cases, there is no question regarding missing evidence that was submitted at prior levels of appeal; but in the few cases in which that is a question, good cause could be found to admit the evidence in accordance with proposed § 405.1028(a)(2)(iv). We also disagree with the commenter who suggested allowing additional flexibility for an ALJ or attorney adjudicator to consider evidence that was not timely submitted in accordance with section 1869(b)(3) of the Act without a statement of good cause, because doing so would be contrary to section 1869(b)(3) of the Act.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1018 and 423.2018 as proposed with the following modifications. We are revising § 405.1018(d) to provide in paragraph (d)(1) that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, and in (d)(2) that the requirement in paragraph (c) to support new evidence with a statement of good cause does not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier. We are also correcting a drafting error and adding a missing comma to § 423.2018(b)(1) and (c)(1) for consistency with § 405.1018(a) and to clarify that there are three time frames when a represented enrollee may submit written or other evidence he or she wishes to have considered with the request for hearing: (1) With the request for hearing; (2) by the date specified in the request for hearing in accordance with § 423.2014(a)(2); or (3) if a hearing

is scheduled, within 10 calendar days of receiving the notice of hearing.

**j. Time and Place for a Hearing Before an ALJ (§§ 405.1020 and 423.2020)**

As described below, we proposed a number of changes to provisions concerning the time and place for a hearing before an ALJ in §§ 405.1020 and 423.2020. 81 FR 43790, 43824–43827. As the ALJ hearing function transitioned from SSA, where hearings could be held at over 140 hearing sites nation-wide, to OMHA with four field offices, OMHA became one of the first agencies to use video-teleconferencing (VTC) as the default mode of administrative hearings. The effective use of VTC mitigated OMHA's reduced geographic presence, and allowed OMHA to operate more efficiently and at lower cost to the American taxpayers. However, the preference of most appellants quickly turned to hearings conducted by telephone. We stated in the proposed rule that, in FY 2015, over 98% of hearings before OMHA ALJs were conducted by telephone. Telephone hearings provide parties and their representatives and witnesses with the opportunity to participate in the hearing process with minimal disruption to their day, and require less administrative burden at even lower cost to the American taxpayers than hearings conducted by VTC. OMHA ALJs also prefer telephone hearings in most instances, because they allow more hearings to be conducted without compromising the integrity of the hearing. However, even if a telephone hearing is being conducted, when the ALJ conducting the hearing believes visual interaction is necessary for a hearing, he or she may conduct a VTC hearing, and when special circumstances are presented, ALJs may conduct in-person hearings.

Despite the shift in preferences for most appellants to telephone hearings, current § 405.1020 still makes VTC the default mode of hearing, with the option to offer a telephone hearing to appellants. In fact, some appellants have required the more expensive VTC hearing even when their representative is presenting only argument and no testimony is being offered. We stated in the proposed rule that we believe this is inefficient and results in wasted time and resources that could be invested in adjudicating additional appeals, and unnecessarily increases the administrative burdens and costs on the government for conducting a hearing with little to no discernable benefit to the parties in adjudicating denials of items or services that have already been furnished. Based on these

considerations, we proposed that a telephone hearing be the default method, unless the appellant is an unrepresented beneficiary. We stated in the proposed rule that we believed that this proposal balances the costs and administrative burdens with the interests of the parties, recognizing that unrepresented beneficiaries may have an increased need and desire to visually interact with the ALJ.

We proposed in § 405.1020(b) to provide two standards for determining how appearances are made, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. We proposed to incorporate the provisions of current § 405.1020(b) into proposed § 405.1020(b)(1), and revise them to specify that they are applicable to an appearance by an unrepresented beneficiary who files a request for hearing. We proposed in subsection (b)(1) that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by VTC if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance. As in the current rule, we also proposed in § 405.1020(b)(1) to allow the ALJ to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary. The current standard for determining whether an in-person hearing should be conducted involves a finding that VTC technology is not available or special or extraordinary circumstances exist. Because, absent special or extraordinary circumstances, a hearing could still be conducted by telephone if VTC technology were unavailable, we proposed that the standard for an in-person hearing be revised to state that VTC or telephone technology is not available or special or extraordinary circumstances exist, and the determination would be characterized as finding good cause for an in-person hearing, to align with current § 405.1020(i)(5), which provides for granting a request for an in-person hearing on a finding of good cause. We also proposed in §§ 405.1020(b)(1) and 405.1020(i)(5) to replace the reference to obtaining the concurrence of the "Managing Field Office ALJ" with the "Chief ALJ or designee." We stated in the proposed rule that the position of the Managing Field Office ALJ became what is now an Associate Chief ALJ, see

80 FR 2708, and using “Chief ALJ or designee” would provide OMHA with the flexibility to designate the appropriate individual regardless of future organizational changes. We proposed to adopt these revisions in proposed § 423.2020(b)(1) for appearances by unrepresented enrollees and § 423.2020(i)(5), for when an ALJ may grant a request for an in-person hearing. We also proposed in § 405.1020(b)(1) to replace “videoteleconferencing,” with “video-teleconferencing,” for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020 and 423.2036.

Section 405.1020(b)(2), as proposed, addresses appearances by an individual other than an unrepresented beneficiary who files a request for hearing. We proposed in § 405.1020(b)(2) that the ALJ would direct that those individuals appear by telephone, unless the ALJ finds good cause for an appearance by other means. Further, we proposed in § 405.1020(b)(2) that the ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal. Also, we proposed that the ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if VTC and telephone technology are not available, or special or extraordinary circumstances exist. We proposed to adopt these revisions in § 423.2020(b)(2) for appearances by represented enrollees, which is more specific than proposed § 405.1020(b)(2) because only enrollees are parties to appeals under part 423, subpart U, and the provisions of subsection (b)(2) would apply only to appearances by represented enrollees.

Current § 405.1020(c)(1) states that the ALJ sends a notice of hearing. This has caused confusion as to whether the ALJ must personally sign the notice, or whether it can be sent at the direction of the ALJ. We believe that the notice may be sent at the direction of the ALJ, and requiring an ALJ signature adds an unnecessary step in the process of issuing the notice. Therefore, we proposed in § 405.1020(c)(1) that a notice of hearing be sent without further qualification, and to let other provisions indicate the direction that is necessary from the ALJ in order to send the notice, such as § 405.1022(c)(1), which provides that the ALJ sets the time and place of the hearing. We proposed to adopt these provisions in § 423.2020(a)(1).

Current § 405.1020(c)(1) also requires that the notice of hearing be sent to the parties who filed an appeal or participated in the reconsideration, any

party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration. However, there are instances in which a party who does not meet the criteria may face liability because the ALJ may consider a new issue based on a review of the record. To address this, we proposed in § 405.1020(c)(1) to add that a party that may be found liable based on a review of the record must be sent a notice of hearing. In addition, current § 405.1020 does not address notices of hearing sent to CMS or a non-QIC contractor. We stated in the proposed rule that, currently, ALJs may also send a notice of hearing to CMS or a contractor when the ALJ believes their input as a participant or party may be beneficial. We proposed in § 405.1020(c)(1) that the notice of hearing also be sent to CMS or a contractor that the ALJ believes would be beneficial to the hearing. We did not propose any corresponding revisions to current § 423.2020(c)(1) because only enrollees are parties to appeals under part 423, subpart U.

OMHA ALJs have expressed concern that parties and representatives who appear at a hearing with multiple individuals and witnesses who were not previously identified, complicate and slow the hearing process. We stated that while a party or representative has considerable leeway in determining who will attend the hearing or be called as a witness, prior notice of those individuals is necessary for the ALJs to schedule adequate hearing time, manage their dockets, and conduct the hearing. To address these concerns, we proposed at § 405.1020(c)(2)(ii) to add a requirement to specify the individuals from the entity or organization who plan to attend the hearing if the party or representative is an entity or organization, and at subsection (c)(2)(iii) to add a requirement to list the witnesses who will be providing testimony at the hearing, in the response to the notice of hearing. We also proposed to consolidate the provisions in current § 405.1020(c)(2)(i) and (c)(2)(ii) in proposed § 405.1020(c)(2)(i) to simplify the provisions related to the current requirements for replying to the notice of hearing. Thus, subsection (c)(2)(i) would require all parties to the ALJ hearing to reply to the notice by acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing. We proposed at § 423.2020(c)(2) to adopt corresponding revisions for an enrollee’s reply to the notice of hearing.

We also proposed in § 405.1020(c)(2) to remove the provision for CMS or a contractor that wishes to participate in the hearing to reply to the notice of hearing in the same manner as a party because a non-party may not object to the proposed time and place of the hearing, or present witnesses. Instead, we proposed in § 405.1020(c)(3) to require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice of hearing by acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing, and specifying who from the entity plans to attend the hearing. We proposed at § 423.2020(c)(3) to adopt corresponding revisions for CMS’s, the IRE’s, or the Part D plan sponsor’s reply to the notice of hearing when the entity requests to attend the hearing as a participant.

In discussing a party’s right to waive a hearing, current § 405.1020(d) states that a party may waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. In light of proposed § 405.1038(b), which would allow attorney adjudicators to issue decisions in appeals that do not require hearings on the record without an ALJ conducting a hearing in certain situations, we proposed in § 405.1020(d) to state that a party also may waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b), but an ALJ may require the parties to attend a hearing if it is necessary to decide the case. We proposed at § 423.2020(d) to adopt corresponding revisions for an enrollee to waive his or her right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b), but an ALJ could require the enrollee to attend a hearing if it is necessary to decide the case. We stated in the proposed rule that these references would direct readers to the section that provides the authority for a decision based on the written record, which would provide them with a complete explanation of when the authority may be used and notify them that an ALJ or attorney adjudicator may issue the decision.

In addressing the ALJ’s authority to change the time or place of the hearing if the party has good cause to object, current § 405.1020(e) requires a party to make the request to change the time or place of the hearing in writing. However, we stated that on occasion, a party may need to request a change on the day prior to, or the day of, a hearing due to an emergency, such as a sudden illness or injury, or inability to get to a

site for the hearing. In this circumstance, we stated in the proposed rule that we believed an oral request should be permitted. Therefore, we proposed in § 405.1020(e)(3) that the request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing, and the ALJ must document the oral request in the administrative record. We proposed at § 423.2020(e)(3) to adopt a corresponding provision for an enrollee to orally request a rescheduled standard hearing, and to modify the documentation requirement, which is currently limited to documenting oral requests made for expedited hearings, to include all oral objections.

In addition, current §§ 405.1020(e)(4) and 423.2020(e)(4), which explain the ALJ may change the time or place of the hearing if the party has good cause, contain a parenthetical that references the procedures that an ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing. The parenthetical does not appear to address or assist in understanding the circumstances covered by current §§ 405.1020(e)(4) and 423.2020(e)(4), and we, therefore, proposed to remove the parenthetical from the respective sections.

Current §§ 405.1020(g)(3) and 423.2020(g)(3) provide a list of examples of circumstances a party might give for requesting a change in the time or place of the hearing. We stated in the proposed rule that we have heard from ALJs and stakeholders that it would be helpful to also include the following two additional examples: (1) The party or representative has a prior commitment that cannot be changed without significant expense, in order to account for circumstances in which travel or other costly events may conflict with the time and place of a hearing, which the ALJ may determine warrants good cause for changing the time or place of the hearing; and (2) the party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place, which the ALJ may determine warrants good cause for changing the time or place of the hearing. We proposed in §§ 405.1020(g)(3)(vii) and (viii), and 423.2020(g)(3)(vii) and (viii) to add these two examples to address these circumstances. We believe these additional examples will provide greater flexibility in the appeals process and better accommodate the needs of appellants.

We proposed in §§ 405.1020(h) and 423.2020(h) to revise the references to the adjudication “deadline” with references to the adjudication “period,” for consistency in terminology with the specified cross-references.

We proposed revisions to § 405.1020(i) to align the provision with proposed § 405.1020(b). We proposed in § 405.1020(i) that if an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ’s offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The party would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held, and the request must be in writing. We proposed in § 405.1020(i)(4) to incorporate the current § 405.1020(i)(4) provision that requires the appeal to be adjudicated within the time frame specified in § 405.1016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. However, we proposed at § 405.1020(i)(4) to revise the language to more accurately state that the ALJ issues a “decision, dismissal, or remand to the QIC,” rather than just a “decision,” within the adjudication time frame specified in § 405.1016. We proposed revisions to § 423.2020(i) to align the provision with proposed § 423.2020(b). We proposed in § 423.2020(i) that if an unrepresented enrollee who filed the request for hearing objects to a VTC hearing or to the ALJ’s offer to conduct a hearing by telephone, or if a represented enrollee who filed the request for hearing objects to a telephone or VTC hearing, the enrollee or representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The enrollee would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held. We proposed in § 423.2020(i)(4) to incorporate the current § 423.2020(i)(4) provision with some modifications so that the appeal would be adjudicated within the time frame specified in § 423.2016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. We proposed at § 423.2020(i)(4) to revise the language to more accurately

state that the ALJ issues a “decision, dismissal, or remand to the IRE,” rather than just a “decision,” within the adjudication time frame specified in § 423.2016 and to include requests for VTC hearings as well as requests for in-person hearings. In addition, we proposed at §§ 405.1020(i)(5) and 423.2020(i)(5) to provide that upon a finding of good cause, a hearing would be rescheduled at a time and place when the party may appear in person or by VTC, to account for objections to VTC hearings as well as objections to telephone hearings or offers to conduct a hearing via telephone. We also proposed to replace “concurrence of the Managing Field Office ALJ” with “concurrence of the Chief ALJ or a designee” because the position of Managing Field Office ALJ was replaced by the position of Associate Chief ALJ (80 FR 2708) and providing a more general reference would provide greater flexibility in the future as position titles change.

Current §§ 405.1020 and 423.2020 do not address what occurs when the ALJ changes the time or place of the hearing. We proposed at § 405.1020(j) to add a provision titled “Amended notice of hearing” to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing, in accordance with the procedures of § 405.1022(a), which addresses issuing a notice of hearing. We proposed at § 423.2020(j) to add a provision to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with the procedures of § 423.2022(a), which addresses issuing a notice of hearing. We stated that these revisions would help ensure that if changes are made to the time or place of the hearing, a new notice is issued or waivers are obtained in a consistent manner.

Provided below are summaries of the specific comments received and responses to these comments:

We received ten comments on the proposed changes to time and place for a hearing before an ALJ. We received five comments on the proposal to make telephone the default method for conducting hearings, except when the appellant is an unrepresented beneficiary, unless an ALJ finds good cause for conducting a hearing by VTC or an in-person hearing. The remaining

comments addressed other aspects of the time and place for hearing before an ALJ and are discussed in further detail below.

*Comment:* Three commenters on behalf of advocacy organizations and one individual commenter, opposed making telephone the default method for conducting hearings for appellants who are not unrepresented beneficiaries. Commenters generally argued that conducting a hearing by telephone reduces due process, but they appreciated the proposal to maintain VTC as the default method for conducting hearings for unrepresented beneficiaries. By contrast, one commenter supported the proposal.

*Response:* We thank the commenter who supports the proposal. We disagree with opposing commenters that telephone hearings reduce due process. We believe that all ALJ hearings currently conducted by OMHA fully protect appellants' rights to procedural due process, and that our proposed changes do not compromise those rights. Furthermore, section 1869(b)(1)(A) of the Act does not specify the manner in which hearings must be held, and in legislation that led to the establishment of OMHA to administer the ALJ hearing program, Congress instructed HHS to explore the possibility of providing hearings using formats other than in-person hearings. Specifically, the MMA instructed HHS to consider the feasibility of conducting Medicare hearings "using tele- or videoconference technologies." See section 931(a)(2)(G) of the MMA.

Under both the current regulations and our proposed changes, procedural safeguards are in place that meet the due process requirements for administrative hearings such as the right to proper notice that a hearing has been scheduled, the right of a party to appear before the ALJ to present evidence and to state his or her position, the right to have a representative present at the hearing, the right to present witnesses and testimony, the right to cross examine witnesses, the right to object to the issues in the notice and/or the hearing method, the right to request and receive a copy of all or part of the record from OMHA (including the hearing audio), and the right to appeal the ALJ's decision. Parties also have the same access to the audio hearing record when appearing by telephone as they would have if appearing by VTC or in-person. In addition, the proposal includes mechanisms in § 405.1020(b) that permit a VTC or in-person hearing if there is a finding of good cause in a given appeal. Given the procedural safeguards existing in the regulations,

we do not believe changing the default method of conducting hearings to telephone hearings for appellants other than unrepresented beneficiaries would compromise an appellant's due process or right to a hearing.

However, while we do not believe that due process requires a hearing that includes a visual component as a matter of right in all cases, we acknowledge that those who are most unfamiliar with legal proceedings, specifically unrepresented beneficiaries, may benefit from the interaction with the ALJ and be more comfortable with a visual component. Thus, the proposal provides two standards for determining how hearings would be conducted, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. We have retained VTC as the default hearing method for unrepresented beneficiaries under § 405.1020(b)(1), unless the ALJ finds good cause for an in-person hearing (note that the ALJ also may offer a telephone hearing in certain circumstances). Under § 405.1020(b)(2) (as discussed below), in appearances by individuals other than unrepresented beneficiaries, telephone hearings are the default hearing method, though the parties may obtain a VTC or in-person hearing if the ALJ finds good cause.

*Comment:* One commenter indicated telephone hearings do not take appreciably less time than VTC hearings, and also OMHA is budgeted to provide VTC hearings and there is no evidence that the volume of VTC hearings in past years has exceeded this line item on OMHA's operational budget.

*Response:* We disagree with the commenter's assertions.

As we stated in the proposed rule (81 FR 43824), in FY2015 alone, over 98% of hearings before OMHA ALJs were conducted by telephone, and in FY2016 over 99% of hearings before OMHA ALJs were conducted by telephone. Contrary to the commenter's assertion, we have learned over eleven years of operation that telephone hearings take less time and are less costly for parties, representatives, and witnesses because telephone hearings do not require travel time or travel expenses for parties to a VTC site. Telephone hearings also provide parties with the opportunity to participate in the hearing process with minimal disruption to the day. Further, telephone hearings take less time for OMHA to schedule and conduct. When a VTC hearing room is reserved or unavailable, scheduling of the hearing is delayed. Support staff must also remain present during the entire duration of a

VTC hearing to assist the ALJ in case the equipment does not operate properly. We believe this is inefficient and can result in wasted staff time and resources that could be redirected to scheduling additional appeals.

Although we acknowledge the volume of VTC hearings in past years has not exceeded OMHA's operational budget, due in part to the fact that a majority of hearings were conducted by telephone, telephone hearings cost less to conduct, and would result in significant savings to the agency and ultimately to the taxpayers. We also believe the money budgeted to provide for the more expensive VTC hearings could instead be reallocated to hire additional support staff and resources to address the backlog. On balance, telephone hearings require less administrative burden to parties and OMHA, at a lower cost to taxpayers.

*Comment:* Commenters who opposed the proposal to make telephone hearing the default method of conducting a hearing for individuals other than unrepresented beneficiaries and supported maintaining VTC as the default method of conducting a hearing argued: (1) VTC is beneficial to ALJs in lengthy hearing sessions "due to the volume of appeals, issues, documentation, and complexity of the arguments being conveyed"; (2) VTC allows a party to show and discuss images of injuries, wounds, and other visual evidence; (3) it is unreasonable to require an appellant to make their case by telephone "where millions of dollars are at stake, or perhaps the very existence of an appellant"; (4) VTC is beneficial where reference to the medical documentation can be cumbersome; and (5) VTC can be particularly valuable in facilitating communication when representatives of appellants have limited familiarity with the OMHA appeals process.

*Response:* Although telephone hearings are the default hearing method under proposed § 405.1020(b)(2), (which we are finalizing in this rule), parties still have the opportunity under that section for a VTC or in-person hearing in certain circumstances. Sections 405.1020(b)(2) and 423.2020(b)(2), as finalized, state the ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone unless the ALJ finds good cause for an appearance by other means. Specifically, the ALJ may find good cause for an appearance by VTC if the ALJ determines VTC is necessary to examine the facts or issues in an appeal. In addition, the ALJ, with the concurrence of the Chief ALJ or

designee, may find good cause for an in-person hearing if VTC and phone technology are not available or special or extraordinary circumstances exist. We believe the situations raised by the commenters who opposed the proposal could be examples where “the ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal,” depending on the facts of a particular appeal. See §§ 405.1020(b)(2)(i) and 423.2020(b)(2)(i). For example, under § 405.1020(b)(2)(i) and 423.2020(b)(2)(i), an ALJ could find that visual interaction is necessary and that there is good cause for a VTC hearing where: (1) The ALJ or appellant raises an issue with an individual’s credibility; (2) a party presents multiple witnesses to provide testimony; or (3) a party wishes to present video/visual evidence. An ALJ may also find good cause where the case presents complex, challenging, or novel issues, such as in appeals with a high volume of claims and a high dollar or overpayment amount. We believe our decision not to provide an exhaustive description of the good cause standard in the regulations would benefit parties by affording an ALJ the flexibility to grant a VTC or an in-person hearing based on factors or circumstances that may be relevant in a particular case, yet unforeseen at this time.

*Comment:* Commenters who opposed the proposal to make telephone hearing the default method of conducting a hearing and supported maintaining VTC as the default method of conducting a hearing argued: (1) The face-to-face aspect of VTC hearings afford greater assurance that ALJs will hear and understand the testimony and arguments being presented; (2) VTC hearings assure ALJs fulfill the duty to provide a fair hearing; and (3) VTC hearings allow an appellant to observe if the ALJ is tired, disinterested, talking to someone else in the room, thumbing through the file, or not referring to the file at all, which cannot be readily observed on a telephone call.

*Response:* A primary function of the ALJ hearing is to allow the parties to present arguments and testimony, and to allow the ALJ to ask questions in order to provide the ALJ with the necessary information to make the findings of fact and conclusions of law in rendering a decision consistent with the applicable authorities. We do not agree that the face-to-face aspect of VTC hearings afford greater assurance that ALJs will hear and understand the testimony and arguments being presented. While the commenters may prefer to see the ALJ during the hearing,

we do not believe a visual connection with the ALJ is necessary in most cases, and in the circumstances in which it may be necessary, the rules being finalized provide for a mechanism to request a VTC or in-person hearing in §§ 405.1020(i) and 423.2020(i). Regardless of how the hearing is conducted, ALJs have a responsibility pursuant to §§ 405.1030(b) and 423.2030(b) to fully examine the issues on appeal and question the parties and other witnesses, ensuring that all necessary testimony is considered, which would continue under these rules as finalized. An appellant can also ascertain whether the ALJ understands the testimony and arguments being presented over telephone, by gauging the ALJ’s reaction to the testimony and arguments, the ALJ’s follow-up questions, and whether the ALJ has lingering questions. The appellant can then provide the ALJ with the necessary clarification to enable the ALJ to make the findings of fact and conclusions of law. Further, the written decision will reflect the testimony and arguments presented at the hearing, and if a party is dissatisfied with the ALJ’s decision, the party may request a review by the Council and, if applicable, indicate what testimony or arguments presented at the hearing were not fully considered.

In addition, we do not believe that visual interaction is necessary to assure appellants that ALJs are fulfilling their duty to provide a fair hearing. OMHA ALJs have a responsibility to ensure both a fully examined and fairly administered hearing, and must fulfill their duties with fairness and impartiality in accordance with section 205(b) of the Act. As discussed above, we believe that all ALJ hearings currently conducted by OMHA fully protect appellants’ rights to procedural due process, including the right to a fair hearing, and that the changes we are finalizing do not compromise those rights. Further, we do not agree that visual interaction is necessary to observe whether the ALJ is tired, disinterested, or talking to someone else in the room, because an appellant can readily observe how the ALJ is acting during a telephone hearing by noting the ALJ’s tone of voice, pauses, and reaction to arguments or responses to questions. Moreover, we note the visual component of the hearing is not recorded or subject to review. However, parties have the same access to the audio hearing record when appearing by telephone as they would have if appearing by VTC or in person. The ALJ and his or her staff may also review the audio hearing record after the hearing is

conducted, which becomes part of the administrative record for other reviewers. Based on the foregoing, we believe that telephone hearings provide sufficient assurances addressed by the commenters.

*Comment:* One commenter suggested that giving ALJs the discretion to find good cause for an appearance by VTC would almost never result in a VTC hearing, and in the commenter’s opinion, the good cause provisions for VTC or in-person hearings is “almost meaningless.”

*Response:* We disagree with the commenter’s assertion that the good cause provision for VTC or in-person hearings is “almost meaningless.” We believe the good cause provisions are meaningful because, as discussed above, an ALJ could find that visual interaction is necessary and that there is good cause for a VTC hearing where the ALJ or appellant raises an issue with an individual’s credibility, a party presents multiple witnesses to provide testimony, or a party wishes to present video/visual evidence. An ALJ may also find good cause where the case presents complex, challenging, or novel issues, such as in appeals with a high volume of claims and a high dollar or overpayment amount. Given the volume of hearing requests and adjudication timeframes imposed by statute, we believe it is reasonable to use a good cause standard to determine when it is appropriate for an ALJ to conduct a VTC hearing for all appellants except unrepresented beneficiaries. In addition, as discussed above, we believe that telephone hearings adequately protect appellants’ rights to procedural due process. In proposed §§ 405.1020(b)(2) and 423.2020(b)(2), which we are finalizing in this rule, we provide for circumstances in which it may be appropriate for the ALJ to provide a VTC or in-person hearing on his or her own initiative, or to grant a request under §§ 405.1020(i) and 423.2020(i) to change the type of hearing scheduled and permit a VTC or in-person hearing. For appellants other than unrepresented beneficiaries, ALJs will evaluate VTC and in-person hearing requests using the good cause standard established in §§ 405.1020(b)(2) and 423.2020(b)(2), and when appropriate grant a request for a VTC or in-person hearing. If an individual appellant believes a request for a VTC or in-person hearing should have been granted and disagrees with the outcome of the appeal, the appellant can request review of the ALJ’s decision by the Council and request that the Council remand the appeal for a new hearing if it believes that the method of conducting the hearing impacted the

outcome of the appeal such that a new hearing using the requested format is necessary.

*Comment:* One commenter indicated the “availability of live testimony distinguishes the ALJ process from the prior levels of appeal, which are limited to written arguments and evidence. The ALJ hearing should not be just another Reconsideration.”

*Response:* We do not believe that § 405.1020, as finalized in this rule, changes the ability to provide live testimony during the ALJ hearing. As discussed above, § 405.1020(b)(2) provides that telephone hearings are the default hearing method for individuals other than unrepresented beneficiaries, but that VTC or in-person hearings may be provided if the ALJ finds good cause. In telephone hearings, as with VTC and in-person hearings, parties are able to provide live testimony, present evidence, and state their positions to an ALJ, as provided in § 405.1036(a)(1), and witnesses are able to provide live testimony as provided under § 405.1036(a)(3). In a telephone hearing, as in a VTC or in-person hearing, there is live interaction between the ALJ and the parties and participants, which is not the case in a reconsideration, which is a decision based solely on review of the record. Further, §§ 405.1030(b) and 423.2030(b), as finalized in this rule, provide the ALJ will fully examine the issues on appeal and question the parties and other witnesses, ensuring that all necessary testimony is considered. We note that under § 405.1020(d), a party may waive the right to a hearing and request a decision based on written evidence in the record. The decision to waive the right to appear at a hearing before an ALJ, which would entail a waiver of the ability to present live testimony, is solely at the discretion of the party. By waiving the right to appear at a hearing, the party would be requesting that the ALJ or attorney adjudicator issue a decision based on the written evidence in the record.

*Comment:* Three commenters requested that the final rule contain a provision to allow an appellant to request rescheduling of the ALJ hearing if the appellant’s witness(es) are not available due to direct patient care duties that may conflict with the scheduled date and time.

*Response:* Sections 405.1020(g)(3)(iv) and 423.2020(g)(3)(iv) already provide that a party may request a change in time and place of the hearing where “a witness who will testify to facts material to a party’s case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.” This

covers the unavailability of a witness as a direct result of patient care responsibility and therefore provides flexibility to accommodate the needs of appellants.

*Comment:* One commenter opposed the proposed changes to § 405.1020(i)(1) and (2), which provide that an unrepresented beneficiary must file their objection to the hearing method in writing and must include the reasons for their objection. The commenter suggested this could prove difficult for many beneficiaries and unrepresented beneficiaries should be afforded the convenience of being allowed to call the ALJ to orally request a change in the hearing method.

*Response:* We disagree with the suggestion. Section § 405.1020(i)(2) and (3) indicate if a party objects to the hearing method, they “must state the reason for the objection” and the objection “must be in writing.” These provisions are not being changed in this final rule, and therefore, the requirement to include the reason for the objection and to file the objection in writing in proposed § 405.1020(i)(2) and (3) would not place any additional burden on the unrepresented beneficiary. Further, OMHA sends a formatted “Response to Notice of Hearing,” to parties who are sent a notice of hearing, to facilitate their response to the notice of hearing, including making any objections. The parties may simply check the boxes in the response to notice of hearing to indicate if they will attend or if they object to the type of hearing. The response to notice of hearing also indicates the standard for changing the type of hearing, and provides examples of good cause for changing the type of hearing. We believe that using the response to hearing form that is sent with the notice of hearing makes the process of objecting to the type of hearing and providing the reasons for the objection relatively easy and convenient for an unrepresented beneficiary. In addition, a contact phone number for the ALJ’s staff is provided in the notice of hearing and OMHA maintains a dedicated beneficiary help line, if a party needs assistance. Given this process, we do not believe it is necessary to allow oral requests to change the hearing method.

*Comment:* One commenter suggested CMS or a contractor should be invited to an ALJ hearing “when an issue in contention involves non-adherence to or violation of a Medicare statute or policy by CMS or a contractor,” in order for CMS or the contractor “to be made aware of the appellant’s concern and to be able to answer any allegations.”

*Response:* Under the current regulations and the regulations as finalized in this rule, the ALJ has the discretion to make the determination of whether the appearance of CMS or a contractor would be beneficial to the hearing and to request that CMS or a contractor participate, and the ALJ will make such determination when warranted based on the facts of and the issues raised in a particular case. Under §§ 405.1020(c) and 423.2020(c) as finalized in this rule, a notice of hearing is sent to CMS or a contractor “that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.” In addition, under §§ 405.1010 and 405.1012, the ALJ can request (but not require) CMS or a contractor to participate in or be a party to any proceedings before the ALJ, including the oral hearing. Under § 423.2010, the ALJ can request (but not require) CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing. In no case is the ALJ permitted to draw any adverse inference if CMS, its contractor, the IRE and/or the Part D plan sponsor decline the request.

*Comment:* One commenter indicated that although the proposed rule permits the ALJ to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary, nowhere does the request for hearing form elicit this information from the beneficiary. This commenter suggested OMHA should add a section or checkboxes to that effect on the hearing request form to facilitate the unrepresented beneficiary’s preference for method of hearing.

*Response:* Proposed § 405.2010(b)(1), which we are finalizing in this rule, provides that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by VTC, or the ALJ may also offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary. We recognize that an unrepresented beneficiary may have an increased desire to visually interact with the ALJ, and therefore this section states the ALJ will direct that the appearance be conducted by VTC. However, this section also explicitly allows the ALJ to offer a telephone hearing if it may be more convenient for the beneficiary. In addition, by practice, OMHA support staff contacts an unrepresented



beneficiary prior to scheduling the hearing to ask for a time, place and/or method of hearing most convenient for the unrepresented beneficiary to facilitate determination of the beneficiary's preference. And, as indicated previously, the form for responding to the notice of hearing, which is sent to parties with the notice of hearing, contains checkboxes and instructions on which boxes to check if a party plans to attend the hearing or if a party objects to the type of hearing, for example, because the proposed method of hearing is not convenient for the party. The form for responding to notice of hearing also explains the standard for changing the time, place and/or method of the hearing, and provides examples of good cause for changing the time, place and/or method of the hearing. Beneficiaries and enrollees with questions or concerns, or who require additional assistance, can call the toll free OMHA beneficiary help line at (844) 419-3358.

*Comment:* One commenter indicated with respect to proposed § 405.1020(j) that there is no requirement that an ALJ notify the parties if they refuse to grant a request for a change in time and/or place of a hearing. The commenter suggested amending the language so that not only must a request for a change to the time and place of a hearing, or the type of hearing, be in writing but that the ALJ be required to respond to the request in writing, even if the ALJ is refusing to change the time and place of a hearing.

*Response:* We believe the original notice of hearing serves as sufficient notice that the hearing will proceed as scheduled. If a party requesting a change to the time and/or place of hearing does not receive an amended notice of hearing granting the party's request, the party can contact the ALJ's staff to confirm that the hearing will proceed as scheduled in the original notice, but should presume that the ALJ did not grant the request for a change to the time and/or place of hearing. If the ALJ grants the request to change the time and/or place of the hearing, § 405.1020(j), as finalized in this rule, provides "an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a)," which would afford the receiving parties and participants with notice at least 20 calendar days before the rescheduled hearing date. This will help ensure that if changes are made to the time and/or place of the hearing, an amended notice is issued with sufficient

time before the rescheduled hearing in a consistent manner, if waivers are not obtained.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1020 and 423.2020 as proposed, with the following modifications. For the reasons discussed in section II.B.3.f.i above, we are revising § 405.1020(c)(1) to state that the notice of hearing is also sent to CMS or any contractor that has elected to participate in the proceedings in accordance with § 405.1010(b). In addition, in the proposed rule (81 FR 43790, 43825), we proposed to adopt in § 423.2020(b)(2) the same revisions as in § 405.1020(b)(2). Section 405.1020(b)(2)(ii)(A), as finalized in this rule, states "VTC and telephone technology are not available." However, we inadvertently included in proposed § 423.2020(b)(2)(ii)(A) the following language: "video-teleconferencing or telephone technology is not available." Consistent with our proposal to adopt the same revisions in § 423.2020(b)(2) as we adopt in § 405.1020(b)(2), we are revising § 423.2020(b)(2)(ii)(A) to state "video-teleconferencing and telephone technology are not available."

k. Notice of a Hearing Before an ALJ and Objections to the Issues (§§ 405.1022, 405.1024, 423.2022, and 423.2024)

As described below, we proposed a number of changes to §§ 405.1022, 405.1024, 423.2022, and 423.2024, concerning notice of a hearing before an ALJ and objections to the issues. 81 FR 43790, 43827-43828. Current § 405.1022(a) provides that a notice of hearing will be mailed or personally served to the parties and other potential participants, but a notice is not sent to a party who indicates in writing that it does not wish to receive the notice. Current § 423.2022(a) provides that a notice of hearing will be mailed or otherwise transmitted, or personally served, unless the enrollee or other potential participant indicates in writing that he or she does not wish to receive the notice. However, currently § 405.1022(a) is limiting because it does not contemplate transmitting the notice by means other than mail or personal service even though technologies continue to develop and notice could be provided by secure email or a secure portal. Also, notices must be sent in accordance with any OMHA procedures that apply, such as procedures to protect personally identifiable information. In addition, the exception in current § 405.1022(a) does not contemplate a scenario in which a potential participant indicates that it does not

wish to receive the notice, as is provided for in current § 423.2022(a). We proposed in §§ 405.1022(a) and 423.2022(a) to address these issues and align the sections by providing that a notice of hearing would be mailed or otherwise transmitted in accordance with OMHA procedures, or personally served, except to a party or other potential participant who indicates in writing that he or she does not wish to receive the notice.

Current §§ 405.1022(a) and 423.2022(a) provide that a notice of hearing does not have to be sent to a party who indicates in writing that it does not wish to receive the notice and that the notice is mailed or served at least 20 calendar days (for Parts A and B and for non-expedited Part D hearings), or 3 calendar days (for expedited Part D hearings) before the hearing. The provisions do not address the situation where a party wishes to receive the notice, but agrees to the notice being mailed fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing, which may be necessary to accommodate an appellant's request to conduct a hearing in fewer than 20 or 3 calendar days. We proposed to revise §§ 405.1022(a) and 423.2022(a) to address this situation by providing the notice is mailed, transmitted, or served at least 20 calendar days (or 3 calendar days if expedited) before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing. However, we note that like a recipient's waiver of receiving a notice of hearing, a recipient's waiver of the requirement to mail, transmit, or serve the notice at least 20 or 3 calendar days (as applicable) before the hearing would only be effective for the waiving recipient and does not affect the rights of other recipients.

Current § 405.1022(b)(1) requires a notice of hearing to contain a statement of the specific issues to be decided and inform the parties that they may designate a person to represent them during the proceedings. These statements of issues take time to develop, and current § 405.1032, which addresses the issues before an ALJ, provides that the issues before the ALJ are all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. Current § 405.1032 also permits an ALJ to consider a new issue at the hearing, if notice of the new issue is provided to all parties before the start of the hearing. To streamline the notice of hearing,

rather than require the notice of hearing to contain a statement of the specific issues to be decided, we proposed in § 405.1022(b)(1) to require the notice of hearing to include a general statement putting the parties on notice that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing. This is consistent with the standard for determining the issues before the ALJ in proposed § 405.1032(a). However, we also proposed in § 405.1022(b)(1) that the notice of hearing also would contain a statement of any specific new issues that the ALJ will consider in accordance with § 405.1032 to help ensure the parties and potential participants are provided with notice of any new issues of which the ALJ is aware at the time the notice of hearing is sent, and can prepare for the hearing accordingly. For example, if in the request for hearing an appellant raises an issue with the methodology used to sample claims and extrapolate an overpayment, and that issue had not been brought out in the initial determination, redetermination, or reconsideration, the issue would be a new issue and the specific issue would be identified in the notice of hearing. To accommodate proposed § 405.1022(b)(1), we proposed that the portion of current § 405.1022(b)(1) that requires the notice of hearing to inform the parties that they may designate a person to represent them during the proceedings would be re-designated as § 405.1022(b)(2), and current subsections (b)(2), (b)(3), and (b)(4) would be re-designated as subsections (b)(3), (b)(4), and (b)(5), respectively. We proposed at § 423.2022(b) to adopt corresponding revisions for notice information in part 423, subpart U proceedings.

Current § 405.1022(c)(1) provides that if the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation. We proposed to replace "ALJ hearing office" with "OMHA" because OMHA is the responsible entity.

Current § 405.1022(c)(2) provides that if a party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her. The reference to an amended notice has caused confusion, as the original notice does not need to be amended unless the hearing is rescheduled. We proposed in § 405.1022(c)(2) to remove the reference

to an "amended" notice of hearing and provide that a copy of the notice of hearing is sent to the party. However, if a party cannot attend the hearing, we proposed in new § 405.1022(c)(3) that the party may request that the ALJ reschedule the hearing in accordance with proposed § 405.1020(e), which discusses a party's objection to the time and place of hearing. We proposed at § 423.2022(c) to adopt corresponding revisions for providing a copy of the notice of hearing if the enrollee did not acknowledge it and states that he or she did not receive it in part 423, subpart U proceedings.

Current § 405.1022(c)(2) provides that if a party did not receive the notice of hearing, a copy of the notice may be sent by certified mail or email, if available. Current § 423.2022(c)(2) provides an additional option to send the copy by fax. However, use of email to send documents that contain a beneficiary's or enrollee's personally identifiable information is not currently permitted by OMHA policy, and faxes must be sent in accordance with procedures to protect personally identifiable information. We proposed in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the references to using email and fax, and to add that a notice may be sent by certified mail or other means requested by the party and in accordance with OMHA procedures. This would provide the flexibility to develop alternate means of transmitting the request and allow OMHA to help ensure necessary protections are in place to comply with HHS information security policies. Finally, the parenthetical in current §§ 405.1022(c)(2) and 423.2022(c)(2) is not applicable. We believe it was attempting to cross-reference the provision related to requesting a rescheduled hearing. Therefore, we proposed in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the parenthetical. As discussed above, proposed §§ 405.1022(c)(3) and 423.2022(c)(3) would address the option for a party to request a rescheduled hearing and contain the correct cross-reference.

Current § 405.1024 sets forth the provision regarding objections by a party to the issues described in the notice of hearing. Current § 405.1024(b) requires a party to send a copy of its objection to the issues to all other parties to the appeal. We proposed to revise § 405.1024(b) to provide that the copy is only sent to the parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing, because we believe sending a copy of

the objection to additional parties is unnecessary and causes confusion for parties who were not sent a copy of the notice of hearing. No corresponding change was proposed in § 423.2024 because only the enrollee is a party.

Current § 405.1024(c) states that an ALJ makes a decision on the objection to the issues either in writing or at the hearing. We proposed to revise § 405.1024(c) to add the option for an ALJ to make a decision on the objections at a prehearing conference, which is conducted to facilitate the hearing, as well as at the hearing. We believe this added flexibility would allow ALJs to discuss the objections with the parties and make a decision on the record before the hearing at the prehearing conference. However, we noted that the ALJ's decision on an objection to the issues at a prehearing conference pursuant to proposed § 405.1024(c) would not be subject to the objection process for a prehearing conference order under § 405.1040(d). We stated in the proposed rule that a decision on an objection to the issues is not an agreement or action resulting from the prehearing conference, but rather the ALJ's decision on a procedural matter for which the ALJ has discretion, and we do not believe the parties should have a right of veto through the prehearing conference order objection process. We also proposed at § 423.2024(c) to adopt a corresponding revision for a decision on an objection to the issues in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received three comments on this proposal. One commenter asked whether a corrected notice of hearing would be sent to all parties who received the initial notice if a mistake, such as a typographical error in the beneficiary's name or the appeal number, was corrected in the response to the notice of hearing submitted by one of the recipients.

*Response:* Under OMHA's current practices, if OMHA staff is made aware of an error, such as a typographical error, in a notice of hearing, OMHA staff will contact the parties to notify them of the correction as soon as possible. This is generally accomplished through a corrected notice of hearing that is sent to all parties who received the initial notice, but may also be accomplished by contacting the parties and any CMS contractors that have elected to be participants or parties by telephone with appropriate documentation of the contact for the record, so that the hearing may proceed as scheduled.

However, we note that if it appears that a party's ability to prepare for the hearing was negatively affected by the error, it may be necessary to reschedule the time and/or place of the hearing and issue an amended notice of hearing, consistent with proposed § 405.1020(j).

*Comment:* Another commenter indicated that the time frame for sending notice of a hearing is too short considering the burden of moving the hearing once it is scheduled, and suggested that OMHA reinstitute a policy of contacting the appellant's representative prior to sending the hearing notice.

*Response:* We did not propose to change the current rule that a notice of hearing is mailed or served at least 20 calendar days before the hearing (or 3 calendar days before the hearing for Part D expedited appeals). These time frames are necessary for scheduling and conducting the hearing as quickly as possible. While some ALJ teams had a practice of contacting the appellant, or the appellant's representative if a representative was involved, before scheduling a hearing, OMHA has not had a policy that required them to do so. Further, we believe that adding a requirement to contact the parties before scheduling a hearing would add administrative burden and slow the hearing process at a time of record workload volume. Our experience is that there are not a large number of requests to reschedule hearings when hearings are scheduled without contacting the appellant, or the appellant's representative if a representative was involved, prior to scheduling the hearing. Moreover, we believe the current standard for mailing or serving a notice of hearing at least 20 calendar days before the hearing, or 3 calendar days before the hearing for Part D expedited appeals, provides sufficient notice and time to prepare for the hearing, and if necessary, request to change the time or place of the hearing if there is good cause to do so, consistent with §§ 405.1020(e) and 423.2020(e).

*Comment:* One commenter supported the proposal to include a generalized statement of the issues, as well as any specific new issues that the ALJ may consider, in the notice of hearing. The commenter suggested that the notice of hearing should include the dates of service and/or the QIC number to help identify the specific claim that is being scheduled for hearing, as well as the name, address, telephone number, and fax number of the OMHA point of contact for any questions.

*Response:* We thank the commenter for its support of our proposal to

include a generalized statement of the issues, as well as any specific new issues that the ALJ may consider, in the notice of hearing. However, we did not propose changing other content requirements for the notice of hearing, and thus we do not believe that it would be appropriate to include the suggested changes in this final rule. With respect to the dates of service of the claims being appealed, we note that under § 405.1014, as finalized in this rule, the request for hearing must contain the dates of service for the claims being appealed, and a copy of the request must be sent to the other parties who were sent a copy of the QIC's reconsideration. The parties who would receive a notice of hearing under § 405.1020(c), as finalized in this rule, would generally also have received a copy of the QIC's reconsideration, and would thus be able to determine the dates of service by comparing the notice of hearing with the request for hearing. With respect to providing an OMHA point of contact, we note that the notices of hearing currently issued by OMHA include a mailing address, phone number, and fax number for the ALJ team assigned to the appeal. We also note that an appellant can find the QIC appeal number associated with an appeal by using AASIS, which provides public access to appeal status information and is accessed through the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)).

*Comment:* One commenter suggested that the requirement to send a copy of any objection to the issues to the other parties should be waived for unrepresented beneficiaries because it adds to the cost and burden of maintaining an appeal.

*Response:* Consistent with our discussion of copy requirements in section II.B.3.g.v of this final rule above, we do not agree that unrepresented beneficiaries should be exempt from the regulatory requirement to send a copy of their objections to the issues to other parties; instead, we believe that unrepresented beneficiaries should be assisted with meeting this requirement. In the event that an unrepresented beneficiary does not fulfill the requirement, OMHA will forward a copy of any objections submitted by the unrepresented beneficiary to the other parties who were sent a copy of the notice of hearing.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1022, 405.1024, 423.2022, and 423.2024 as proposed without modification.

l. Disqualification of the ALJ or Attorney Adjudicator (§§ 405.1026 and 423.2026)

As described below, we proposed several changes to § 405.1026, which provides a process for a party to request that an ALJ disqualify himself or herself from an appeal, or for an ALJ to disqualify himself or herself from an appeal on the ALJ's own motion. 81 FR 43790, 43828. We proposed to revise § 405.1026 to replace the current references to conducting a hearing with references to adjudicating an appeal, to make it clear that disqualification is not limited to ALJs or cases where a hearing is conducted to help ensure that an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), also cannot adjudicate an appeal if he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision. Current § 405.1026(b) requires that, if a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw. However, the current rule does not address appeals for which no hearing is scheduled and/or no hearing will be conducted. Therefore, we proposed to revise § 405.1026(b) to require that if a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. We also proposed to revise § 405.1026(c) to state that an ALJ or attorney adjudicator is "assigned" to adjudicate an appeal, rather than "appointed," for consistency in terminology, and to replace "hearing decision" with "decision or dismissal" because not all decisions are issued following a hearing and an appellant may have objected in an appeal that was dismissed, for which review may also be requested from the Council. In addition, we proposed to add "if applicable" in discussing that the Council would consider whether a new hearing is held because not all appeals may have had or require a hearing. We proposed at § 423.2026 to adopt corresponding revisions for disqualification of an ALJ or attorney adjudicator in part 423, subpart U proceedings.

Section 405.1026 does not address the impact of a party's objection and adjudicator's withdrawal on an

adjudication time frame. We stated in the proposed rule that the withdrawal of an adjudicator and re-assignment of an appeal will generally cause a delay in adjudicating the appeal. We proposed in new § 405.1026(d) that if the party objects to the ALJ or attorney adjudicator, and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any applicable adjudication time frame that applies is extended by 14 calendar days. We stated that this would allow the appeal to be re-assigned and for the new adjudicator to review the appeal. We proposed at § 423.2026(d) to adopt a corresponding provision for the effect of a disqualification of an adjudicator on an adjudication time frame in part 423, subpart U proceedings, but proposed that if an expedited hearing is scheduled, the time frame is extended by 2 calendar days, to balance the need for the newly assigned adjudicator to review the appeal, and the enrollee's need to receive a decision as quickly as possible.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter asked what recourse is available when, in the opinion of an appellant, an ALJ has not considered arguments, evidence, or testimony to the satisfaction of the appellant in its prior cases assigned to that ALJ. The commenter questioned whether the regulations should allow parties to enter a "peremptory challenge" to an assigned ALJ without explanation as to the reason for requesting that the ALJ withdraw from adjudicating an assigned appeal.

*Response:* Proposed §§ 405.1026 and 423.2026, which we are finalizing in this rule, extend the current provisions related to disqualifying an ALJ based on bias or a conflict of interest, to disqualifying an attorney adjudicator, to help ensure that the same standards and process for disqualifying an adjudicator at OMHA applies regardless of whether the adjudicator is an ALJ or attorney adjudicator. We believe that this is a necessary change to extend the safeguards in current §§ 405.1026 and 423.2026 to cases assigned to an attorney adjudicator. In response to the commenter's question about the recourse available when an appellant believes an ALJ has not considered arguments, evidence, or testimony to the satisfaction of the appellant in its prior cases assigned to the ALJ, in such a situation, to the extent the appellant believes that the ALJ is prejudiced or partial to any party in the case at hand, the appellant could object to the

assigned ALJ and request that the ALJ withdraw from an appeal using the procedures in §§ 405.1026 or 423.2026, as finalized in this rule. If the ALJ does not withdraw, the objection can be raised on appeal to the Council after the ALJ issues a disposition of the case. Similarly, any disagreement with the ALJ's decision, including the ALJ's consideration or analysis of the arguments, evidence, and testimony, could be raised in requesting a review of the decision by the Council.

With regard to the commenter's suggestion that the regulations should allow a peremptory challenge by which a party can request reassignment to a different adjudicator without providing a specific objection, we disagree. We do not believe that preemptory challenges would be appropriate or necessary at the OMHA level. A peremptory challenge is generally a feature of a trial by jury that allows attorneys for each side to reject a limited number of jurors without stating a reason for the challenge and without the judge's approval. The concept of a peremptory challenge is to allow both sides to contribute to the jury's composition to help ensure an unbiased result. Under 5 U.S.C. 3105, ALJs must be assigned to cases in rotation so far as practicable, and current §§ 405.1026 and 423.2026 help ensure an unbiased result by requiring the ALJ to withdraw if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

We believe allowing parties to request reassignment of an ALJ without explaining the basis for objecting to the ALJ is contrary to the principles of random rotational assignments and would be disruptive and inefficient in processing appeals. The recommendation would add a new administrative burden in reassigning appeals, resulting in an overall decrease in the efficient adjudication of appeals. Furthermore, we believe that the option of a peremptory challenge would further increase administrative burdens and inefficiencies in cases involving multiple parties, where the option of a preemptory challenge would need to be extended to all parties to the appeal. In addition, permitting an appellant to exercise a peremptory challenge in the manner suggested may lead to abuses such as forum shopping or retaliation against an ALJ or an attorney adjudicator for a prior decision with which the party did not agree, even if the ALJ's decision was supported by the evidence and affirmed on appeal to the Council. Also, preemptory challenges potentially used for reasons that have nothing to do with bias would go

unrebutted and may undermine the public's confidence in the appeals process. We believe that the potential for abuse, and the administrative burdens and inefficiencies associated with allowing a peremptory challenge outweigh any potential benefit to the adjudication process. In addition, we believe that the disqualification process in §§ 405.1026 and 423.2026 as finalized in this rule, and the opportunity to appeal to the Council any objection to an ALJ or the decision in a case if the ALJ does not withdraw, afford appellants and other parties with strong protections and remedies to address potential bias. The process outlined in §§ 405.1026 and 423.2026 contemplates that the party specify his or her reasons for objecting to the assigned adjudicator so that the adjudicator may consider the reasons and make an informed decision as to whether he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision, and therefore whether to proceed with the appeal or withdraw as the adjudicator. If the adjudicator does not withdraw, the party may request review of the adjudicator's action by the Council. When a reason is provided for the party's objection, even if it is a cursory reason, it is preserved in the record and the Council's review will therefore be better informed. Because the regulations already provide a process by which a party can object to an assigned adjudicator, and an opportunity to have the Council review the objections in cases where an adjudicator does not withdraw, we do not believe a peremptory challenge is necessary.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1026 and 423.2026 as proposed without modification.

#### m. Review of Evidence Submitted by the Parties (§ 405.1028)

As discussed below, we proposed several revisions to § 405.1028, which addresses the prehearing review of evidence submitted to the ALJ. 81 FR 43790, 43828–43830. We proposed to revise the title of § 405.1028 to reflect that the regulation would more broadly apply to the review of evidence submitted by the parties because a hearing may not be conducted and an attorney adjudicator would review evidence in deciding appeals as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above).

We proposed at § 405.1028(a) to incorporate current § 405.1028(a) to address new evidence. Current

§ 405.1028(a) states that after a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier, to determine whether there was good cause for submitting evidence for the first time at the ALJ level. However, this provision and the other provisions in current § 405.1028 do not address the review of new evidence when no hearing is conducted for an appeal. Therefore, we proposed to revise § 405.1028(a) to add § 405.1028(a)(1), (2), (3), and (4), and proposed in § 405.1028(a)(1) that after a hearing is requested but before it is held by an ALJ (to reinforce that hearings are only conducted by ALJs), or a decision is issued if no hearing is held, the ALJ or attorney adjudicator would review any new evidence. In addition, we proposed in § 405.1028(a)(1) to remove the duplicative statement indicating the review is conducted on “any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018,” because § 405.1018 discusses when evidence may be submitted prior to a hearing and, as explained in section III.A.3.i of the proposed rule and II.B.3.i of this final rule above, proposed § 405.1018 would revise the language that is duplicated in current § 405.1028. We stated in the proposed rule that we believed that the better approach going forward is simply to reference § 405.1018 by indicating that the review is conducted on “any new evidence submitted in accordance with § 405.1018.” This would remind parties that evidence must be submitted in accordance with § 405.1018, while minimizing confusion on which section is authoritative with regard to when evidence may be submitted.

In a 2012 OIG report on the ALJ hearing process (OEI-02-10-00340), the OIG reported concerns regarding the acceptance of new evidence in light of the statutory limitation at section 1869(b)(3) of the Act on new evidence submitted by providers and suppliers. The OIG concluded that the current regulations regarding the acceptance of new evidence provide little guidance and only one example of good cause, and recommended revising the regulations to provide additional examples and factors for ALJs to consider when determining good cause.

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC

reconsideration unless there is good cause which precluded the introduction of such evidence at or before that reconsideration. We stated in the proposed rule that this section presents a Medicare-specific limitation on submitting new evidence, and therefore limits the authority of an ALJ to accept new evidence under the broader APA provisions (see 5 U.S.C. 556(c)(3) (“Subject to published rules of the agency and within its power, employees presiding at hearings may— . . . receive relevant evidence . . . .”). We also stated that section 1869(b)(3) of the Act presents a clear intent by Congress to limit the submission of new evidence after the QIC reconsideration, which must be observed.

In light of the OIG conclusion and recommendation and to more effectively implement section 1869(b)(3) of the Act, we proposed to incorporate current § 405.1028(b) in proposed § 405.1028(a)(2) on when an ALJ could find good cause for submitting evidence for the first time at the OMHA level, and to establish four additional circumstances in which good cause for submitting new evidence may be found. We also proposed to permit an attorney adjudicator to find good cause because attorney adjudicators would be examining new evidence in deciding appeals on requests for an ALJ hearing as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), and we stated in the proposed rule that we believed the same standard for considering evidence should apply.

We proposed in § 405.1028(a)(2)(i) to adopt the example in current § 405.1028(b) and provide that good cause is found when the new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC’s reconsideration and that issue was not identified as a material issue prior to the QIC’s reconsideration.

We proposed in § 405.1028(a)(2)(ii) to provide that good cause is found when the new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b). This would provide parties with an opportunity to submit new evidence to address a new issue that was identified after the QIC’s reconsideration. We stated, however, that the authority is limited to ALJs because, as discussed in proposed § 405.1032, only an ALJ may raise a new issue on appeal.

We proposed in § 405.1028(a)(2)(iii) to provide that good cause is found when the party was unable to obtain the evidence before the QIC issued its

reconsideration and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. For example, if specific medical records are necessary to support a provider’s or supplier’s claim for items or services furnished to a beneficiary, the provider or supplier must make reasonable attempts to obtain the medical records, such as requesting records from a beneficiary or the beneficiary’s physician when it became clear the records are necessary to support the claim, and following up on the request. We stated in the proposed rule that obtaining medical records, in some cases from another health care professional, and submitting those records to support a claim for services furnished to a beneficiary is a basic requirement of the Medicare program (see sections 1815(a) and 1833(e) of the Act, and § 424.5(a)(6)), and we expect instances where records cannot be obtained in the months leading up to a reconsideration should be rare. We stated that if the provider or supplier was unable to obtain the records prior to the QIC issuing its reconsideration, good cause for submitting the evidence after the QIC’s reconsideration could be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration.

We proposed at § 405.1028(a)(2)(iv) to provide that good cause is found when the party asserts that the evidence was submitted to the QIC or another contractor and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the new evidence was indeed submitted to the QIC or another contractor before the QIC issued the reconsideration. For example, if a provider or supplier submitted evidence to the QIC or another contractor and, through administrative error, the evidence was not associated with the record that is forwarded to OMHA, good cause may be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration.

Finally, we proposed at § 405.1028(a)(2)(v) to provide that in circumstances not addressed in proposed paragraphs (i) through (iv), the ALJ or attorney adjudicator may find good cause for new evidence when the

ALJ or attorney adjudicator determines the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration. We stated in the proposed rule that we expected proposed paragraphs (i) through (iv) to cover most circumstances in which a provider or supplier attempts to introduce new evidence after the QIC reconsideration, but we also stated that we believed this additional provision is necessary to allow for a good cause finding in any other circumstance that meets the requirements of section 1869(b)(3) of the Act. We stated that paragraph (v) helps ensure that OMHA fulfills the statutory requirement by requiring that the ALJ or attorney adjudicator make a determination on whether the party could have obtained the evidence before the QIC issued its reconsideration.

To accommodate the new structure of proposed § 405.1028, we proposed that current paragraphs (c) and (d) be re-designated as paragraphs (a)(3) and (a)(4), respectively. In addition, we proposed at § 405.1028(a)(4) that notification about whether the evidence would be considered or excluded applies only when a hearing is conducted, and notification of a determination regarding new evidence would be made only to parties and participants who responded to the notice of hearing, since all parties may not be sent a copy of the notice of hearing or attend the hearing. We noted that if a hearing is not conducted, whether the evidence was considered or excluded would be discussed in the decision, pursuant to proposed § 405.1046(a)(1), as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below. We also proposed at § 405.1028(a)(4) that the ALJ would notify all parties and participants whether the new evidence would be considered or is excluded from consideration (rather than only whether the evidence will be excluded from the hearing) and that this determination would be made no later than the start of the hearing, if a hearing is conducted. We stated that if evidence is excluded, it is excluded from consideration at all points in the proceeding, not just the hearing, and evidence may be excluded from consideration even when no hearing is conducted. We stated that we believe that this would provide greater clarity to parties and participants regarding the ALJ's determination with respect to new evidence, and the effect of the exclusion of such evidence on the proceedings.

Current § 405.1028 does not address duplicative evidence. We stated in the proposed rule that duplicative evidence

is a significant challenge for OMHA because appellants often submit copies of medical records and other submissions that were filed at prior levels of appeal and are in the record forwarded to OMHA. While we recognize that appellants want to ensure the evidence is in the record and considered, we are also mindful that the APA provides that as a matter of policy, an agency shall provide for the exclusion of unduly repetitious evidence (see 5 U.S.C 556(d)).

We proposed in § 405.1028(b) that the ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA. In addition to establishing a general policy for the exclusion of unduly repetitious evidence, we stated that this would reduce confusion as to which of the multiple copies of records to review, and would reduce administrative burden.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter expressed support for allowing providers to submit evidence that may have been unavailable at the lower levels of appeal.

*Response:* We believe the commenter was referring to our proposal in § 405.1028(a)(2)(iii) to allow for the submission of new evidence when a party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. We thank the commenter for its support.

*Comment:* We received a comment recommending that the proposed language in § 405.1028(a) be modified to give the ALJ or attorney adjudicator discretion to admit new evidence, despite a party's inability to satisfy one of the examples of "good cause" listed in the regulation, when the adjudicator determines that "review of additional evidence is necessary in the interest of justice."

*Response:* We disagree with the recommendation. Section 1869(b)(3) of the Act establishes a specific prohibition on a provider or a supplier submitting evidence that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the evidence from being introduced at or before the QIC's reconsideration. This statutory provision limits the submission of new

evidence by certain appellants late in the administrative appeals process, and provides an exception only if there is good cause which precluded the introduction of such evidence at or before the reconsideration. We believe that the standard suggested by the commenter could incorporate exceptions that are inconsistent with the good cause standard set forth in the statute. We believe that the enumerated examples in the regulations of when an ALJ or attorney adjudicator may find good cause for new evidence submitted by a provider or supplier for the first time at OMHA effectively implements section 1869(b)(3) of the Act and provides those parties with clearer guidance as to what is permissible under section 1869(b)(3). We believe that the enumerated good cause examples listed in § 405.1028(a)(2) balance the interests of the parties in maintaining an avenue through which new evidence may be admitted for consideration while remaining faithful to the statutory requirement of section 1869(b)(3) of the Act.

*Comment:* One commenter expressed concern with proposed § 405.1028(b), noting that the new language on duplicative evidence does not address the procedures that will be used to determine if a record is a duplicate or how a provider can request that a record omitted in error is placed back in the record. The commenter suggested that if records are removed, all parties to the appeal should have the opportunity to review the administrative record prior to a hearing to ensure that the record is complete.

*Response:* Pursuant to the procedures outlined in §§ 405.1042(b) and 423.2042(b) as finalized in this rule, parties may request a copy of the administrative record to review at any time while the appeal is pending at OMHA, including prior to the hearing. In addition, parties are provided with an opportunity to reference and discuss specific records or other evidence at the hearing, to confirm that the exhibited portion of the administrative record contains all the evidence that the ALJ will consider. Section 405.1028(b), as finalized in this rule, only provides that documents that are duplicative may be identified as such and, on that basis, are not marked as exhibits and are excluded from consideration. This section does not permit duplicative evidence to be removed from the administrative record, thus the documents are preserved and may be re-designated and placed back in the exhibited portion of the administrative record if it is determined that the document was identified as duplicative in error. The procedures for

identifying and handling duplicates are outlined in the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency. The OCPM describes OMHA case processing procedures in greater detail and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)), includes a detailed chapter on the administrative record and provides instructions on identifying and handling duplicative evidence.

*Comment:* Another commenter noted that the proposed changes allow attorney adjudicators to determine if a party has good cause for submitting evidence for the first time at the OMHA level or to exclude duplicative evidence from consideration. In the commenter's opinion, such judgments should be reserved for ALJs.

*Response:* We disagree with the commenter and believe that attorney adjudicators will have the necessary skills and training to address procedural determinations regarding whether there is good cause for submitting evidence for the first time at the OMHA level, which will be aided by the additional guidance in proposed § 405.1028, and to identify or confirm that evidence is duplicative of evidence already in the record. As discussed in section II.A.2 of this final rule above, well-trained attorneys can perform a review of the administrative record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision on the matter. We believe that the procedural determinations regarding whether there is good cause for new evidence and whether evidence is duplicative are necessary for attorney adjudicators to establish the record upon which a decision will be made, and the determinations are not so complex as to require an ALJ. Moreover, allowing attorney adjudicators to make these procedural determinations on evidence in their cases will allow for ALJs to focus more of their time and attention on appeals that require a hearing, and the more complex procedural issues involved in those appeals.

*Comment:* One commenter requested that health plans be allowed the opportunity to respond to the submission of new evidence and indicate whether the plan believes good cause does not exist, why the case may require a remand for consideration of the new evidence, or why the newly provided evidence should not be afforded any weight in the adjudicator's decision.

*Response:* As discussed above (and section III.A.3.m of the proposed rule), the requirement that providers, suppliers, and beneficiaries represented by providers and suppliers, present any evidence for an appeal no later than the QIC reconsideration level, unless there is good cause for late submission, emanates from section 1869(b)(3) of the Act and is an existing regulatory requirement at §§ 405.1018 and 405.1028. Health plans are not parties to fee-for-service appeals conducted under section 1869 of the Act and, as explained in section II.A.3 of this final rule above (and section II.C of the proposed rule), we do not believe the part 405 regulatory requirements that implement section 1869(b)(3) of the Act are applicable to Part C MA appeals or cost plan appeals, because there is no similar requirement in section 1852(g) or 1876 of the Act. There is also no similar requirement in section 1860–D4 of the Act, and the Part D appeals regulations at part 423, subparts M and U have not implemented such a requirement. Therefore, we do not believe there would be any situations where a party would be required to make a showing of good cause for the introduction of new evidence in a Part C or Part D appeal in which a health plan was also a party. We note that § 423.2018(a)(2) does require an ALJ to remand an appeal to the Part D IRE when an enrollee wishes evidence on his or her change in condition after a coverage determination to be considered, but this is compulsory under the regulations and not subject to ALJ discretion. Furthermore, although parties are permitted to respond to new evidence that is admitted into the administrative record, making a determination of whether good cause exists, whether a case requires a remand to the lower level, or whether evidence submitted should or should not bear weight in the decision are all assessments that are the responsibility of the adjudicator and are not subject to party or participant input. We believe that adding party or participant input to these types of adjudicator actions undermines the adjudicator's role, and would result in unnecessary delays to an appeal, which is contrary to our goal of streamlining the appeals process.

*Comment:* One commenter urged OMHA to firmly reinforce with all ALJs, attorney adjudicators, and other staff that the limitation on submitting new evidence for the first time at the OMHA level does not apply to unrepresented beneficiaries and Medicaid State agencies.

*Response:* We agree with the commenter and note that the current

regulation at § 405.1028(a) states that the limitations apply only when new evidence is submitted by a provider, supplier, or a beneficiary represented by a provider or supplier. As discussed in section II.B.3.i of this final rule above, we are amending proposed § 405.1018(d) to provide that the limitation on submitting new evidence for the first time at the OMHA level does not apply to evidence submitted by unrepresented beneficiaries, CMS or its contractors, a Medicaid State agency, an applicable plan, or beneficiaries represented by someone other than a provider or supplier. Current § 405.1018(d) already explicitly states that the limitations on submitting evidence, including the limitations on the submission of new evidence, do not apply to an unrepresented beneficiary. In addition, OMHA provides training to its ALJs, attorneys, and other staff to help ensure understanding and compliance with all regulations applicable to processing appeals, and will provide training on all aspects of this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 405.1028 as proposed without modification.

n. ALJ Hearing Procedures (§§ 405.1030 and 423.2030)

The APA provides an ALJ with the authority to regulate the course of a hearing, subject to the rules of the agency (see 5 U.S.C. 556(c)(5)). As discussed below, we proposed several revisions to §§ 405.1030 and 423.2030, which address ALJ hearing procedures. 81 FR 43790, 43830–43832. We stated in the proposed rule that in rare circumstances, OMHA ALJs have encountered a party or representative that makes it difficult or impossible for the ALJ to regulate the course of a hearing, or for other parties to present their side of the dispute. This may occur when a party or representative continues to present testimony or argument on a matter that is not relevant to the issues before the ALJ, or on a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. This may also occur when a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. Sections 405.1030 and 423.2030 set forth the rules that govern ALJ hearing procedures. We proposed to revise §§ 405.1030(b) and 423.2030(b) to add provisions to address these circumstances in a consistent manner that protects the interests of the parties



and the integrity of the hearing process. To accommodate these proposals, we proposed to re-designate paragraph (b) in both §§ 405.1030 and 423.2030 as paragraph (b)(1), and, to be consistent with proposed §§ 405.1018 and 423.2018, to replace the current language stating that an ALJ may accept “documents that are material to the issues” with “evidence that is material to the issues,” because not all evidence that may be submitted is documentary evidence (for example, photographs).

We proposed in § 405.1030(b)(2) to address circumstances in which a party or representative continues with testimony and argument that are not relevant to the issues before the ALJ or that address a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. In these circumstances, the ALJ may limit testimony and/or argument at the hearing, and may, at the ALJ’s discretion, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing, within a time frame designated by the ALJ. Proposed § 405.1030(b)(2) would allow the ALJ to effectively regulate the course of the hearing by providing the ALJ with the clear authority to limit testimony and/or argument during the hearing, while providing an avenue for the ALJ to allow the testimony and/or argument to be entered into the record. We proposed at § 423.2030(b)(2) to adopt a corresponding revision for limiting testimony and argument at a hearing, and at the ALJ’s discretion, provide an opportunity to submit additional written statements and affidavits in part 423, subpart U proceedings.

We proposed at § 405.1030(b)(3) to address circumstances in which a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. In these circumstances, we proposed that the ALJ would have the clear authority to excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with the opportunity to offer testimony and/or argument. However, we stated in the proposed rule that in this circumstance, the ALJ would be required to provide the excused party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Further, we stated that the party also would be allowed to request a copy of the audio recording of the hearing in accordance with § 405.1042 and respond in writing to any

statements made by other parties or participants and/or testimony of the witnesses at the hearing, within a time frame designated by the ALJ. These proposals would allow the ALJ to effectively regulate the course of the hearing and balance the excused party’s right to present his or her case, present rebuttal evidence, and cross-examine the witnesses of other parties with allowing the party to submit written statements and affidavits. We proposed at § 423.2030(b)(3) to adopt a corresponding revision for excusing an enrollee or representative who is uncooperative, disruptive, or abusive during the hearing in part 423, subpart U proceedings.

Current § 405.1030(c) addresses evidence that the ALJ determines is missing at the hearing, and provides that if the evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine whether the appellant had good cause for not producing the evidence earlier. We proposed to revise § 405.1030(c) to add that the ALJ must determine whether the appellant had good cause in accordance with § 405.1028 for not producing the evidence. Section 1869(b)(3) of the Act applies to limit submission of all new evidence after the QIC reconsideration by a provider or supplier absent good cause, and the proposed addition would create consistent application of the standards for determining whether there is good cause to admit new evidence, regardless of when the evidence is submitted after the QIC reconsideration. We did not propose any corresponding changes to current § 423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.

Current § 405.1030(d) and (e) discuss what happens if an ALJ determines there was or was not good cause for not producing the new evidence earlier. Current § 405.1030(d) provides that if the ALJ determines that good cause exists, the ALJ considers the evidence in deciding the case, and the adjudication period is tolled from the date of the hearing to the date that the evidence is submitted. Current § 405.1030(e) provides that if the ALJ determines that good cause does not exist, the evidence is excluded, with no impact on an applicable adjudication period. We stated in the proposed rule that current § 405.1030(d) and (e) have caused confusion in light of § 405.1018, which indicates that the adjudication period will be affected if evidence is submitted later than 10 calendar days after receipt

of the notice of hearing, unless the evidence is submitted by an unrepresented beneficiary. We stated that it has also potentially created an incentive for appellants to disregard § 405.1018 because current § 405.1030(b) appears to allow evidence to be submitted at the hearing without affecting the adjudication time frame; and § 405.1030(c) allows the ALJ to stop a hearing temporarily if there is material evidence missing, with the effect of tolling the adjudication time frame (under § 405.1030(d)) from the date of the hearing to the date the evidence is submitted, if the evidence is in the possession of an appellant who is a provider or supplier or beneficiary represented by a provider or supplier, and the ALJ finds good cause to admit the evidence. In addition, we stated that OMHA ALJs have expressed concern that current § 405.1030(e) does not affect the adjudication period when an equal amount of time is spent reviewing evidence and making a good cause determination, regardless of whether good cause is found.

Therefore, we proposed to revise § 405.1030(d) to address the effect of an evidentiary submission on an adjudication period. We proposed in § 405.1030(d) that any applicable adjudication period is extended in accordance with proposed § 405.1018(b) if an appellant other than an unrepresented beneficiary submits evidence pursuant to proposed § 405.1030(b), which generally allows for submission of evidence at the hearing, or proposed § 405.1030(c), which specifically addresses evidence that the ALJ determines is missing at the hearing. Under proposed § 405.1018(b), any adjudication period that applies to the appeal would be extended by the number of days starting 10 calendar days after receipt of the notice of hearing, and ending when the evidence is submitted, whether it is at the hearing pursuant to proposed § 405.1030(b)(1), or at a later time pursuant to proposed § 405.1030(c). We stated that proposed § 405.1030(d) would provide appellants with an incentive to submit evidence they wish to have considered early in the adjudication process, allow the ALJ to consider the evidence and effectively prepare for the hearing, and minimize any delays in the adjudication process resulting from the late introduction of evidence during the hearing process. We further stated that proposed § 405.1030(d) would also remove the potential incentive to disregard § 405.1018, and reconcile any inconsistency in the effect of a late evidentiary submission on an applicable

adjudication period by incorporating the § 405.1018 provisions by reference rather than establishing a different standard for evidence submitted during the course of or after a hearing. We proposed at § 423.2030(d) to adopt a corresponding provision for the effect on an adjudication time frame when new evidence is submitted by a represented enrollee in a standard appeal, or an unrepresented or represented enrollee in an expedited appeal, in accordance with current § 423.2018(b) or (c), as applicable.

Continuing a hearing is referenced in current § 405.1030(c), but is not otherwise addressed in part 405, subpart I. We proposed in § 405.1030(e)(1) that a hearing may be continued to a later date and that the notice of the continued hearing would be sent in accordance with proposed § 405.1022, except that a waiver of the notice of hearing may be made in writing or on the record, and the notice of continued hearing would be sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate. We stated in the proposed rule that the notice requirement would help ensure that the general hearing notice requirements are met for a continued hearing, but allow a waiver of the notice of hearing to be made in writing or on the record. We stated that we believe the added option of waiving the notice of hearing on the record in the context of a continued hearing would facilitate scheduling the continued hearing when all parties and participants who are in attendance at the hearing agree to the continued hearing date, or alternatively agree on the record to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing. In addition, proposed § 405.1030(e)(1) would only require that a notice of the continued hearing be sent to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants. We stated that we believe that a notice of the continued hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the continuance and an adjudication period applies to the appeal, we proposed in § 405.1030(e)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the continued hearing

date. We stated that we believe an appellant's request for a continuance of the hearing is similar to an appellant's request to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We proposed at § 423.2030(e) to adopt corresponding provisions for continued hearings in part 423, subpart U proceedings.

On occasion, after a hearing is conducted, ALJs find that additional testimony or evidence is necessary to decide the issues on appeal, or a procedural matter needs to be addressed. Current § 405.1030(f) allows an ALJ to reopen a hearing to receive new and material evidence pursuant to § 405.986, which requires that the evidence (1) was not available or known at the time of the hearing, and (2) may result in a different conclusion. However, current § 405.1030(f) does not provide a mechanism to address procedural matters, or to obtain additional information through evidence or testimony that may have been available at the time of hearing and may result in a different outcome but the importance of which was not recognized until after a post-hearing review of the case. We proposed in § 405.1030(f)(1) to remove the "reopen" label and provide for a "supplemental" hearing rather than reopening the hearing to distinguish it from reopening a decision and the standards for reopening a decision. We also proposed that a supplemental hearing may be conducted at the ALJ's discretion at any time before the ALJ mails a notice of decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. We stated in the proposed rule that the ALJ would determine whether a supplemental hearing is necessary, and if one is held, the scope of the supplemental hearing, including when evidence is presented and what issues are discussed. In addition, we proposed at § 405.1030(f)(1) that a notice of the supplemental hearing be sent in accordance with § 405.1022 to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants the ALJ determines are appropriate. Similar to the proposed notice of a continued hearing explained above, we stated that we believe that a notice of the supplemental hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise

based on the circumstances of the case. In the event that the appellant requested the supplemental hearing and an adjudication period applies to the appeal, we proposed at § 405.1030(f)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the supplemental hearing date. We stated that we believe an appellant's request for a supplemental hearing is similar to an appellant's request for a continuance or to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We proposed at § 423.2030(f) to adopt corresponding provisions for supplemental hearings in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received two comments opposed to the language in proposed §§ 405.1030(b)(2) and 423.2030(b)(2) permitting an ALJ to limit the testimony and argument at the hearing. The commenters believed that the proposals undercut an appellant's ability to get a full and fair hearing, and expressed concern that the language gives too much discretion to ALJs in allowing an ALJ to limit testimony and/or argument if the ALJ determines that he or she has sufficient information and in permitting the ALJ to decide whether to allow additional written submissions. The commenters also noted that an ALJ hearing is the first, and in some appeals only, time where an appellant can provide oral argument, and the commenters urged that under no circumstances should an appellant be prevented from presenting what the appellant deems to be a full argument to the ALJ.

*Response:* We believe our proposal strikes a necessary balance between protecting the interests of the parties and protecting the integrity of the hearing process. OMHA ALJs have sometimes encountered a party or representative that continues to present testimony or argument at a hearing that is not relevant to the issues before the ALJ, that is repetitive of evidence or testimony already in the record, or that relates to an issue that has been sufficiently developed or on which the ALJ has already ruled. When the testimony or argument is unrelated to an issue on appeal or an ALJ determines that additional evidence or testimony on the issue would be repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed or on which he or she has already ruled, the

continued testimony or argument becomes repetitive or unnecessarily cumulative, and adds nothing of value to the proceedings. This continued testimony and argument is not only an inefficient use of time and resources for the ALJ and the parties, it may have the effect of monopolizing the time set for a hearing and causing other parties to limit their presentations because they have only allowed for the scheduled hearing time in their schedules.

We do not believe that limiting testimony that is unrelated, repetitive, or related to an issue that has been sufficiently developed or upon which the ALJ has already ruled prejudices a party's right to a full and fair hearing. ALJs have a responsibility pursuant to current §§ 405.1030(b) and 423.2030(b) to fully examine the issues on appeal, ensuring that all necessary testimony is considered, which would continue under these rules as finalized. The proposals at §§ 405.1030(b) and 423.2030(b), which we are finalizing in this rule, would only limit the introduction of repetitive or unrelated evidence. Moreover, the proposal is based on the APA at 5 U.S.C. 556(c)(5), which provides that subject to the published rules of the agency, an ALJ may regulate the course of the hearing. We believe that ALJs, who have a responsibility to ensure both a fully examined and fairly administered hearing, will use these provisions only in the limited situations that the proposals are intended to address.

With regard to the concern that the proposed regulations give too much discretion to the ALJ, we believe such discretion is consistent with and authorized by the APA. As we stated above, we believe the ALJ needs to be able to effectively regulate the course of the hearing, including the exercise of discretion as outlined in the §§ 405.1030(b) and 423.2030(b), as finalized, in order to effectively protect the interest of parties and to preserve the integrity of the hearing process.

*Comment:* The same two commenters noted that limiting testimony could negatively impact appeals to the Council since the Council limits its review to the evidence in the record of the proceedings before the ALJ.

*Response:* We disagree that the proposals at §§ 405.1030(b)(2) and 423.2030(b)(2) will negatively impact appeals to the Council. Although the commenters refer to the language in § 405.1122(a)(1) stating that when the Council is reviewing an ALJ's decision, the Council limits its review to the evidence contained in the record of the proceedings before the ALJ, that regulation goes on to say in

§ 405.1122(a)(2) that if the Council determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. A party that feels that certain evidence was not duly entered into the record because of an ALJ's decision to limit testimony at the hearing pursuant to the proposed regulations may appeal that issue to the Council. The hearing is preserved on audio recording and is available for review on appeal, and the Council may remand a case if the record shows that the party is entitled to a new hearing.

*Comment:* Another commenter specifically objected to the language in proposed §§ 405.1030(b)(2) and 423.2030(b)(2) permitting an ALJ to limit testimony or argument on the basis that "the ALJ believes he or she has sufficient information." The commenter stated that limiting testimony and argument on that basis is dangerous precedent, potentially interrupts the logical flow of an argument, precludes an appellant from knowing what the ALJ understands and prevents the appellant from being able to build a rational case upon a common knowledge base. The commenter noted that some fields of medicine change rapidly and even though an ALJ may have recently heard and decided a similar case for a similar condition, due to the evolving information in the field, ALJs may not come into the hearing with sufficiently up-to-date information.

*Response:* We disagree with the commenter's suggestion that proposed §§ 405.1030(b)(2) and 423.2030(b)(2) could be used to limit argument or testimony related to new or updated information relevant to an issue on appeal. The language in the proposed regulations that the commenter specifically opposes is focused on testimony or argument that is unnecessarily repetitive because the ALJ has determined that he or she has sufficient information to make an informed decision or has already ruled on the issue. As we stated above, an ALJ is responsible for fully examining the issues on appeal and therefore an ALJ cannot limit testimony or argument in the situation described by the commenter where a full examination requires additional updated or new information. However, we understand that the passage stating, "ALJ determines he or she has sufficient information" may not be widely understood and may be subject to varying interpretations, and we are

therefore finalizing proposed §§ 405.1030(b)(2) and 423.2030(b)(2) with modification to clarify the intent of the provision as discussed above. Specifically, we are modifying §§ 405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. We believe this modification clarifies the intent of this provision and will mitigate the possibility that the provision would be used to limit argument or testimony related to new or updated information relevant to an issue on appeal.

With regard to the commenter's concern that limiting testimony or argument would interrupt the logical flow of an argument or make it difficult for the party to present a coherent or rational case, we note that these concerns appear to relate mainly to a party being able to present its case in the manner that he or she believes is most logical, coherent, or rational and do not adequately recognize the ALJ's role in the process. When an ALJ limits testimony or argument at the hearing, it is because the ALJ believes the testimony or argument was not relevant to an issue before the ALJ, was repetitive of evidence or testimony already in the record, or related to an issue that was sufficiently developed, and the ALJ has heard all necessary testimony, understands the arguments being made, and is able to logically, rationally, and fully analyze the issue to make a decision. Moreover, we believe these concerns about being able to present a case in the order and manner an individual desires are outweighed by the ALJ's broader responsibilities to protect the interests of all parties and preserve the integrity of the hearing process. As we discuss above, allowing a party to continue presenting testimony and argument when the testimony or argument is not relevant to an issue before the ALJ, is repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed, is not only an inefficient use of time and resources, it may have the effect of monopolizing the time set for a hearing and causing other parties to limit their presentations because they have only allowed for the scheduled hearing time in their schedules.

*Comment:* Another commenter noted that ALJs may improperly use the discretion afforded in proposed §§ 405.1030(b)(2) and 423.2030(b)(2) to

get through hearings faster or set unreasonably short periods of time for hearings that involve large numbers of cases.

*Response:* While efficient use of time and resources is an important interest, §§ 405.1030(b)(2) and 423.2030(b)(2), as finalized, do not provide authority to curtail hearings or limit appellants' presentations of evidence, argument, or testimony solely for the purpose of keeping the duration of a hearing within a specified time parameter. Given the ALJ's responsibility to examine the issues fully at the hearing, as discussed above, we do not believe that §§ 405.1030(b)(2) and 423.2030(b)(2) would be abused by ALJs as suggested by this comment, and to the extent that a party believes that inadequate time was provided and the ALJ did not provide additional time, that issue could be raised on appeal to the Council.

*Comment:* One commenter recommended modifying the proposed changes in §§ 405.1030(b)(3) and 423.2030(b)(3) to clarify that a party will only be excused from a hearing after an initial admonishment of the party's conduct by the ALJ.

*Response:* We agree that the recommended modification would provide better clarity to parties regarding the expectations or concerns of an ALJ during the course of a hearing and would provide a fair warning to parties that they must adjust their behavior or risk being excused from the hearing. We have therefore further modified proposed §§ 405.1030(b)(3) and 423.2030(b)(3) to state that an ALJ may excuse the party, enrollee, or representative from the hearing if that party, enrollee, or representative remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has given a warning.

*Comment:* One commenter expressed concern that the proposed regulations allowing an ALJ to excuse a party that is uncooperative, disruptive, or abusive during the hearing will be misconstrued to limit the ability of appellants to make their arguments and curtail due process. The commenter stressed that a high bar therefore should be imposed on the use of proposed §§ 405.1030(b)(3) and 423.2030(b)(3). The commenter argued that proposed §§ 405.1030(b)(3) and 423.2030(b)(3) would permit an ALJ to excuse a party or representative when a hearing becomes "spirited or contentious" and that parties and representatives may refrain from objecting to certain hearing procedures set by the ALJ because they do not want to risk alienating the ALJ and/or being

excused from the hearing. The commenter also argued that even though proposed §§ 405.1030(b)(3) and 423.2030(b)(3) require that the ALJ provide the excused party or representative with an opportunity to submit written statements in lieu of testimony and/or argument at hearing, it would be impossible for an appellant to effectively present a case or cross examine witnesses in writing when the hearing continues without him or her.

*Response:* We anticipate that ALJs would rarely find the need to use the rules at proposed §§ 405.1030(b)(3) and 423.2030(b)(3) to excuse someone from the hearing but believe that the proposals are necessary to protect the integrity of the hearing process. An ALJ has authority to regulate the course of the hearing, consistent with § 556(c) of the APA and §§ 405.1030 and 423.2030, which we believe includes excusing any party or representative that is being disruptive to the adjudication process. Especially with the additional modification discussed above requiring an initial warning by the ALJ, we believe §§ 405.1030(b)(3) and 423.2030(b)(3), as finalized, satisfactorily balance the excused party's right to present his or her case with the ALJ's authority to regulate the course of the hearing. As we note above, ALJs have a responsibility under current §§ 405.1030(b) and 423.2030(b) (and §§ 405.1030(b)(1) and 423.2030(b)(1) as finalized in this rule) to fully examine the issues on appeal. We believe that ALJs, who have a responsibility to ensure both a fully examined and fairly administered hearing, will use these provisions infrequently and only when necessary to support a full and fair hearing.

We note that any party that is excused from the hearing pursuant to proposed §§ 405.1030(b)(3) and 423.2030(b)(3) would be permitted to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Although the commenter noted that written statements would limit an excused party's or representative's ability to present a case or cross examine witnesses and other parties at the hearing, we believe that the required warning would effectively put the excused entity or individual on notice of the consequences of continued uncooperative, disruptive, or abusive behavior, and therefore the excused individuals or entities would have knowingly limited their own argument and testimony to written statements by continuing such behavior. While the format of the argument and testimony would be changed, we disagree with the commenter that written statements and

affidavits are necessarily less effective or persuasive than oral argument or testimony or that they curtail due process. The ALJ would give the same weight to argument or testimony that is presented in writing as to argument or testimony that is presented orally at the hearing. Moreover, any excused party would be able to request a copy of the audio recording of the hearing in accordance with §§ 405.1042 and 423.2042 so that the party could respond in writing to any statements or testimony made at the hearing, including the submission of rebuttal argument and evidence.

Finally, we disagree with the commenter's characterization that the type of behavior addressed in §§ 405.1030(b)(3) and 423.2030(b)(3) is synonymous with "spirited or contentious" or that parties or their representatives would refrain from objecting to certain hearing procedures set by the ALJ because they do not want to risk being excused from the hearing. The language used in the regulations—uncooperative, disruptive, or abusive—was specifically chosen to describe a certain degree of behavior that makes it difficult or impossible for an ALJ to regulate the course of a hearing or for other parties to present their side of the dispute. We believe that §§ 405.1030(b)(3) and 423.2030(b)(3) are necessary in order to allow the ALJ to effectively regulate the course of the hearing, including providing the other parties with their opportunity to offer testimony and/or argument. To the extent that a party believes it was inappropriately excused from a hearing, that issue could be raised on appeal to the Council.

*Comment:* We received one comment that supported the authority given in proposed §§ 405.1030(b)(3) and 423.2030(b)(3) allowing an ALJ to excuse a party or representative that is disruptive or abusive during the course of the hearing, but requested clarification of the term "uncooperative" as used in the proposed regulations. The commenter asked if it would be seen as "uncooperative" if a party disagrees with an ALJ's interpretation of the law.

*Response:* We thank the commenter for its support of §§ 405.1030(b)(3) and 423.2030(b)(3) and agree that ALJs need to have authority to excuse parties or representatives if they are being disruptive or abusive during the course of the hearing. We also believe that ALJs should have the authority to excuse parties or representatives who are uncooperative because uncooperative behavior can similarly disrupt the course of the hearing and/or negatively

impact the integrity of the hearing process. While uncooperative behavior may take a range of forms, generally we believe that, in the context of §§ 405.1030(b)(3) and 423.2030(b)(3), “uncooperative” is behavior that has risen to a level that is impeding the ALJ’s ability to regulate the hearing or the other parties’ ability to present their side of the dispute. If a party disagrees with an ALJ, as suggested by the commenter’s question, even if the disagreement is spirited or contentious as another commenter suggested, such behavior would not rise to the level of “uncooperative” if it does not impede the ALJ’s ability to regulate the hearing or the other parties’ ability to present their case. We believe that the additional modification discussed above, adding that a party or representative may only be excused after the ALJ has warned the party or representative to stop the disruptive, abusive, or uncooperative behavior, will assist in providing clarity to parties regarding the expectations or concerns of an ALJ during the course of a hearing, and would provide a fair warning to parties and representatives that they must adjust their behavior or risk being excused from the hearing.

*Comment:* We received one request that CMS prepare basic informational documents that may be furnished to or accessed by any party whose testimony has been limited or who has been excused from a hearing, explaining their rights and options under the regulations.

*Response:* Any party who believes that his or her testimony has been unduly limited or who has been excused from a hearing pursuant to proposed § 405.1030(b)(2) or (3), or § 423.2030(b)(2) or (3) may appeal the issue to the Council for review after the ALJ’s decision has been issued. The hearing is preserved on audio recording and is available for review on appeal and the Council may remand a case if the record shows that the party is entitled to a new hearing. We intend to issue additional sub-regulatory guidance in the OCPM, but do not believe that a written document outlining a party’s rights under § 405.1030(b)(2) or (3) or an enrollee’s rights under § 423.2030(b)(2) or (3) is necessary because the party, enrollee, or the party’s or enrollee’s representative, would be informed prior to being excused from the hearing of the right under § 405.1030(b)(3) or § 423.2030(b)(3) to submit written statements and affidavits in lieu of testimony or argument at the hearing. Furthermore, when an ALJ limits testimony and/or argument at the hearing under § 405.1030(b)(2) or

§ 423.2030(b)(2) because the testimony and/or argument is not relevant to an issue before the ALJ, is repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed or on which the ALJ has already ruled, no additional rights or options extend to the party or enrollee other than to appeal the ALJ’s action to the Council. Rather, the ALJ may, but is not required to, provide the party, enrollee, or representative with an opportunity to submit additional written statements and affidavits on the matter.

*Comment:* One commenter asked for additional clarification regarding the statement that “[w]e are not proposing any corresponding changes to current § 423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.”

*Response:* Part 423, subpart U includes detailed procedures for requesting and adjudicating a request for hearing or a request for review of a dismissal under Medicare Part D (the Voluntary Medicare Prescription Drug Benefit). The preamble to the final rule establishing the Medicare Part D claims appeals process issued in the **Federal Register** on December 9, 2009 (74 FR 65340) sets forth that the provisions of part 423, subpart U generally follow the part 405, subpart I procedures. However, there are some specific differences between the part 405, subpart I rules governing Medicare Part A and B appeals and the part 423, subpart U rules governing Medicare Part D appeals, including the absence of good cause limitations for the introduction of new evidence in Medicare Part D proceedings as discussed in the proposed and final Part D appeals rules (73 FR 14345, 74 FR 65345). In the final Medicare Part D appeals rule (74 FR 65345), we decided that the full and early presentation of evidence provisions of part 405 subpart I, including § 405.1028, would not apply in Part D appeals. As discussed above, section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the reconsideration, unless there is good cause which precluded the introduction of evidence at or before the reconsideration. Part 405, subpart I extends this requirement to beneficiaries represented by providers or suppliers in an effort to ensure that providers or suppliers do not attempt to circumvent the full and early presentation of evidence rules by offering to represent beneficiaries. In the proposed and final Part D appeals rules (73 FR 14345, 74 FR 65345), we noted

our desire to provide enrollees with as much flexibility as possible concerning the evidence that may be presented for an ALJ hearing and Council review, and stated that because an enrollee is the only party to the appeal in Medicare Part D cases, and because an enrollee would not be represented by a provider or supplier attempting to circumvent this rule, we were not including in the part 423, subpart U rules any provisions from part 405, subpart I on the full and early presentation of evidence. This flexibility extends to the submission of any written evidence about an enrollee’s condition at the time of the coverage determination. However, the subpart U rules do provide that if an enrollee wishes to have evidence on changes in his or her condition since the coverage determination considered in the appeal, an ALJ or the Council will remand the case to the Part D IRE. Accordingly, although the Medicare Part A and Part B regulations (part 405, subpart I) contain language limiting the submission of new evidence after the QIC reconsideration (see, for example, §§ 405.1018, 405.1028, and 405.1030), the corresponding Medicare Part D regulations (part 423, subpart U) do not contain that language.

The only proposed change to § 405.1030(c)—the provision regarding procedures when an ALJ determines that there is material evidence missing at the hearing in Medicare Part A and Part B cases—is to add a reference to § 405.1028 for consistency regarding the application of the standards for determining whether there is good cause to admit new evidence regardless of when the evidence is submitted after the QIC reconsideration. No changes were proposed for § 423.2030(c)—the corresponding provision regarding procedures when an ALJ determines that there is material evidence missing at the hearing in Medicare Part D cases—because there is no corresponding language requiring good cause for the admission of new evidence in the Medicare Part D regulations as explained above.

*Comment:* We received one comment on proposed § 405.1030(d) requesting that Medicaid State agencies be explicitly exempted, similar to unrepresented beneficiaries, from any extension of the adjudication period if new evidence is submitted at the hearing.

*Response:* Medicaid State agencies, in addition to unrepresented beneficiaries, CMS and its contractors, applicable plans, and beneficiaries represented by someone other than providers or suppliers, are not subject to the same limitations on the submission of new

evidence after the QIC reconsideration as providers and suppliers are under section 1869(b)(3) of the Act. As discussed in section II.B.3.i above, we have modified language in § 405.1018(d) to provide that those individuals and entities are exempt from the requirement to show good cause for the late submission of evidence. We do not agree, however, that because individuals and entities other than unrepresented beneficiaries are not subject to the good cause requirements for the submission of late evidence that they should also be afforded the same treatment as unrepresented beneficiaries with respect to exemption from extension of the adjudication period when new evidence is submitted. We believe that individuals and entities other than unrepresented beneficiaries are generally more familiar with the appeals process than unrepresented beneficiaries, and are generally aware that evidence to be considered in deciding an appeal should be submitted as early in the process as possible (see also §§ 405.946 and 405.966). Further exempting individuals and entities—other than unrepresented beneficiaries—who are already exempt from the requirement to show good cause for the introduction of new evidence after the QIC reconsideration from an extension of the adjudication period could incentivize these individuals and entities to delay the submission of evidence until after a hearing has been scheduled, and possibly conducted. We believe this could have a detrimental effect on an ALJ's ability to issue a timely decision. Furthermore, we note that §§ 405.946 and 405.966 provide for extensions to the time frames for issuing a redetermination and reconsideration, respectively, when a party submits additional evidence after filing the request for redetermination or reconsideration. Our modification in § 405.1018(d) makes it clear that although those entities are exempt from the requirement of submitting a statement and demonstrating good cause for new evidence, they are still subject to an extension on the applicable adjudication period pursuant to § 405.1018(b), as they are under current § 405.1018(b) and (d). To be consistent with the rules in § 405.1018 regarding new evidence, we decline to make the commenter's suggested change to § 405.1030(d).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1030 and 423.2030 as proposed,

with the following modifications. We are revising §§ 405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. In addition, we are revising §§ 405.1030(b)(3) and 423.2030(b)(3) to add language that a party or party's representative (or enrollee or enrollee's representative in the context of § 423.2030(b)(3)) may be excused from a hearing if that individual remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior.

o. Issues Before an ALJ or Attorney Adjudicator (§§ 405.1032, 405.1064 and 423.2032)

As described below, we proposed several changes to §§ 405.1032 and 423.2032, which address the issues that are before the ALJ. 81 FR 43790, 43832–43834. We proposed to revise the title of the section to indicate that the proposed provision also would apply to issues before an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), if an attorney adjudicator is assigned to an appeal.

Current § 405.1032(a) states that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, we stated in the proposed rule that when a request for hearing involves a reconsideration of multiple claims and the appellant does not identify one or more of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, it is unclear whether the ALJ should review all of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, or just those claims specified by the appellant in the request for hearing. An appellant is required to identify the dates of service for the claims that it wishes to appeal in its request for hearing under § 405.1014, and some appellants have indicated that they do not specify a denied claim in a request for hearing when they agree that the record does not support coverage of the claim. To address the ambiguity, and in the interest of efficiency and consistency with § 405.1014, we proposed in § 405.1032(a) that the issues

before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter (for example, for appeals that do not involve a claim for items or services furnished to a beneficiary, such as Medicare Secondary Payer appeals and terminations of coverage) specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. We proposed at § 423.2032(a) to adopt a corresponding revision for issues in part 423, subpart U proceedings, except the term claims is not used because part 423, subpart U appeals do not involve claims.

Current § 405.1032(a) also notes that if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ notifies the parties before the hearing and may consider it an issue at the hearing. As explained in the 2005 Interim Final Rule (70 FR 11462), this provision relates to the favorable portion of an appealed claim, and that the favorable issue is a new issue that must meet the requirements of current paragraph (b). However, in practice, this provision has been read to allow consideration of separate claims that were decided in a party's favor at lower appeal levels in multiple-claim appeals, and at times read independently from paragraph (b). To address this confusion, we proposed to move this language in § 405.1032(a) to proposed § 405.1032(b), with the revisions discussed below. We proposed at § 423.2032(a) and (b) to adopt corresponding revisions for new issues in part 423, subpart U proceedings.

Current § 405.1032(b) allows new issues to be considered at the hearing if: (1) The ALJ notifies the parties about the new issue before the start of the hearing; (2) the resolution of the new issue could have a material impact on the claim or claims that are the subject of the request for hearing; and (3) its resolution is permissible under the rules governing reopening of determinations and decisions. We proposed at § 405.1032(b) to incorporate these provisions, with the revisions discussed below, as well as the language regarding consideration of favorable issues moved from current § 405.1032(a), in a revised structure.

We proposed in § 405.1032(b)(1) to address when a new issue may be considered. Specifically, we proposed that the ALJ may only consider the new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or

appealed matter, and (1) there is new or material evidence that was not available or known at the time of the determination and which may result in a different conclusion, or (2) the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination. We stated in the proposed rule that this would consolidate the current provisions to better convey when a new issue may be considered, clarify that a new issue relates to a claim or appealed matter specified in the request for hearing, and provide the applicable standards from the reopening rules referenced in current § 405.1032(b)(1)(ii). We proposed in § 405.1032(b)(1) to continue to provide that the new issue may be raised by the ALJ or any party and may include issues resulting from the participation of CMS, but also to correct the language so that it also references participation of CMS contractors. We proposed at § 423.2032(b)(1) to adopt corresponding revisions for when new issues may be considered in part 423, subpart U proceedings.

We proposed at § 405.1032(b)(2) to continue to provide that notice of the new issue must be provided before the start of the hearing, but would limit the notice to the parties who were or will be sent the notice of hearing, rather than the current standard to notice "all of the parties." Because notice of the new issue may be made in the notice of hearing or after the notice of hearing, and parties generally have 10 calendar days after receipt of the notice of hearing to submit evidence, we proposed at § 405.1032(b)(3) to also provide that if notice of the new issue is sent after the notice of hearing, the parties would have at least 10 calendar days after receiving the notice of the new issue to submit evidence regarding the issue. As provided in proposed § 405.1028(a)(2)(ii), the ALJ would then determine whether the new evidence is material to the new issue identified by the ALJ. We also stated in the proposed rule that if an adjudication time frame applies to the appeal, the adjudication period would not be affected by the submission of evidence. Further, we proposed at § 405.1032(b)(3) that if the hearing is conducted before the time to submit evidence regarding the issue expires, the record would remain open until the opportunity to submit evidence expires to provide the parties sufficient time to submit evidence regarding the issue. We proposed at § 423.2032(b)(2) and (b)(3) to adopt corresponding provisions for providing notice of new issues to enrollees and an

opportunity to submit evidence, and to add that an enrollee will have 2 calendar days after receiving notice of the new issue in an expedited appeal to submit evidence, which corresponds to the length of time permitted under proposed § 423.2018(c) to submit evidence after receiving a notice of expedited hearing.

Current § 405.1032(c) states that an ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless the claim has been adjudicated at the lower appeal levels and all parties are notified of the new issues before the start of the hearing. However, in practice, we are unaware that this provision is used, and to the extent it may be used, we believe it would be disruptive to the adjudication process, result in filing requirements not being observed, and risk adjudication of the same claim by multiple adjudicators. Therefore, we proposed to maintain the topic of adding claims to a pending appeal, but replace the language of current § 405.1032(c), as explained below.

A reconsideration may be appealed for an ALJ hearing regardless of the number of claims involved in the reconsideration. However, we recognize that a party may not specify all of the claims from a reconsideration that he or she wishes to appeal in the party's request for hearing. We proposed in § 405.1032(c)(1) to address this circumstance by providing that claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed in the request for hearing, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims to be added in accordance with proposed § 405.1014(e). We stated in the proposed rule that we believe that this would result in less disruption to the adjudication process, greater adherence to filing requirements, and reduce the risk of adjudication of the same claim by multiple adjudicators. To help ensure that the copy requirement of proposed § 405.1014(d) is observed, we proposed at § 405.1032(c)(2) to require that before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates that the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in

accordance with § 405.1014(d). We proposed at § 423.2032(c) to adopt a provision corresponding to proposed § 405.1032(c)(1), but we did not propose to adopt a provision corresponding to § 405.1032(c)(2) because there is no § 423.2014 requirement for an enrollee to send a copy of his or her request to others.

Current § 405.1032 does not address issues related to an appeal that involves a disagreement with how a statistical sample and/or extrapolation was conducted. When an appeal involves a statistical sample and an extrapolation and the appellant wishes to challenge how the statistical sample and/or extrapolation was conducted, as discussed previously, we proposed at § 405.1014(a)(3)(iii) to require the appellant to assert the reasons the appellant disagrees with how the statistical sampling and/or extrapolation was conducted in the request for hearing. We proposed at § 405.1032(d)(1) to reinforce this requirement by excluding issues related to how the statistical sample and/or extrapolation were conducted if the appellant does not comply with § 405.1014(a)(3)(iii). In addition to reinforcing the proposed requirement at § 405.1014(a)(3)(iii), we stated in the proposed rule that we believed that excluding the issue is appropriate because an appellant should reasonably be aware of whether it disagrees with how the statistical sampling and/or extrapolation was conducted at the time it files a request for hearing, and raising the issue later in the adjudication process or at the hearing can cause significant delays in adjudicating an appeal because the ALJ may need to conduct additional fact finding, find it necessary to request participation of CMS or one of its contractors, and/or call expert witnesses to help address the issue.

Related to the issues that an ALJ must consider, the 2005 Interim Final Rule (70 FR 11466) explained that current § 405.1064 was added to set forth a general rule regarding ALJ decisions that are based on statistical samples because a decision that is based on only a portion of a statistical sample does not accurately reflect the entire record. As discussed in the 2009 Final Rule (74 FR 65328), current § 405.1064 explains that when an appeal from the QIC involves an overpayment, and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of all claims in the sample. However, we stated in the proposed rule that while a review of the claims selected for the sample is necessary to review issues related to a



contested sample and extrapolation, for example to determine whether the sample claims were appropriately selected for a representative sample of the universe, current § 405.1064 has been read more broadly to also require adjudication of each sample claim, regardless of whether the sample claim was adjudicated favorably at lower appeal levels. We further stated in the proposed rule that we do not believe adjudicating sample claims that were decided favorably at lower levels of appeal, or sample claims that are not appealed by a party, is necessary to adjudicate broader issues with how sampling and extrapolation was conducted, and that the broader reading of current § 405.1064 results in unnecessary adjudications of claims that were not appealed.

To clarify what is at issue and what must be considered in appeals involving statistical sampling and extrapolations, we proposed to remove current § 405.1064, and address the matter in § 405.1032(d)(2). We proposed in § 405.1032(d)(2) that if a party asserts a disagreement with how the statistical sampling methodology and extrapolation were conducted in the request for hearing, in accordance with proposed § 405.1014(a)(3)(iii), § 405.1032(a) through (c) would apply to the adjudication of the sample claims. The result of applying proposed § 405.1032(a) and (b) would be that only the sample units that were specified in the request for hearing are individually adjudicated, subject to a new issue being identified for an appealed claim. However, proposed § 405.1032(c) would permit adding sample claims to a pending appeal if they were adjudicated in the appealed reconsideration and the time to request a hearing on the reconsideration has not expired, or the ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e). To incorporate the principle embodied in current § 405.1064, we proposed in § 405.1032(d)(2) that in deciding issues related to how a statistical sample and/or extrapolation was conducted, the ALJ or attorney adjudicator would base his or her decision on a review of the entire sample to the extent appropriate to decide the issue. We stated in the proposed rule that we believed this more clearly conveys the intent of the rule and recognizes that an individual adjudication of each claim in the sample is not always necessary to decide an issue related to how a statistical sample and/or extrapolation was conducted, such as whether there is documentation so that the sampling frame can be re-

created, as required by the Medicare Program Integrity Manual (Internet-Only Manual 100–08) (see chapter 8, section 8.4.4.4.1). We did not propose any corresponding changes in § 423.2030 because statistical sampling and extrapolation are not currently used for matters that are subject to part 423, subpart U proceedings.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter noted that there were numerous changes proposed in part 405, subpart I concerning standards for ALJs to consider new issues, notice requirements for new issues, the submission and admissibility of evidence related to new issues, and rules governing whether claims may be added to a pending appeal. The commenter suggested that, if the proposals were finalized, OMHA publish “an expanded beneficiary handbook (online and elsewhere) that explains these provisions in ‘practical, understandable terms for the layperson.’”

*Response:* We thank the commenter for the suggestion, and will consider providing beneficiaries with enhanced or additional tools to help them understand the appeals process in the future. Although we proposed many revisions to the existing rules in part 405, subpart I and other provisions that apply to benefit appeals, one of the stated goals of this rulemaking was to streamline and improve the efficiency of the appeals process. We believe many of the proposed changes add clarity to the rules and resolve areas of longstanding confusion for appellants, adjudicators, and other stakeholders in the appeals process. Wherever possible, we have used plain language and have defined terms that may be unfamiliar to beneficiaries or other appellants. However, because the rules sometimes involve complex procedures that require precise terminology (more often associated with provider and supplier appeals), there are instances where oversimplification of a stated rule could have the unintended consequence of introducing further areas of ambiguity and frustrating one of the primary purposes of this rulemaking.

In addition to existing CMS resources like the Medicare & You Handbook, 1–800 Medicare, chapter 29 of the Medicare Claims Processing Manual (Internet-Only Manual 100–4), and the Medicare claims appeals Web site at [www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html](http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html), OMHA is currently in the process of developing

and releasing the OCPM. The OCPM provides day-to-day operating instructions, policies, and procedures based on statutes, regulations, and OMHA directives. Development is ongoing, and although the OCPM is primarily intended to be a resource used by OMHA adjudicators and staff, chapters are made publicly available on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)) soon after they are published. The instructions and guidance in the OCPM describe many policies and procedures in greater detail and provide frequent examples to aid understanding.

OMHA also has a toll free beneficiary help line for Medicare beneficiaries and Part C or Part D plan enrollees who have questions about or need assistance with a request for an ALJ hearing, as well as a separate OMHA national toll free assistance line for other appellants. Information about both help lines can be found on the “Contact OMHA” portion of the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)).

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals to revise §§ 405.1032 and 423.2032 and to remove § 405.1064 without modification.

p. Requesting Information From the QIC or IRE, and Remanding an Appeal (§§ 405.1034, 405.1056, 405.1058, 423.2034, 423.2056, and 423.2058)

Current §§ 405.1034 and 423.2034 describe when an ALJ may request information from, or remand a case to a QIC or IRE. When the ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, including an IRE, or the Part D plan sponsor, current §§ 405.1034(a) and 423.2034(a) allow an ALJ to remand the case to the QIC or IRE that issued the reconsideration, or retain jurisdiction of the case and request that the entity forward the missing information to the appropriate hearing office. The 2005 Interim Final Rule (70 FR 11465) explained that in the rare instance in which the file lacks necessary technical information that can only be provided by CMS or its contractors, it was believed that the most effective way of completing the record is to return the case, via remand, to the contractor; however, the ALJ also had the option of asking the entity to forward the missing information to the ALJ hearing office. We stated in the proposed rule that, in practice, stakeholders have expressed frustration and concern with the remand provisions

because in accordance with the definition of a remand in § 405.902, a remand vacates the lower level appeal decision and therefore may require a QIC or IRE to issue a new reconsideration, for which the appellant must submit a new request for hearing, which causes additional delay in reaching finality on the disputed claims. In addition, current §§ 405.1034 and 423.2034 do not address providing notice of a remand or the effects of a remand.

To address stakeholders' concerns with the current remand provisions, and areas not addressed in current §§ 405.1034 and 423.2034, we proposed to revise the sections to cover obtaining information that can be provided only by CMS or its contractors, or the Part D plan sponsor, and establishing new §§ 405.1056 and 405.1058 to address remands to a QIC, and new §§ 423.2056 and 423.2058 to address remands to an IRE. 81 FR 43790, 43834–43836.

We proposed in § 405.1034(a) to maintain the current standards for requesting information that is missing from the written record when that information can be provided only by CMS or its contractors, but limit the action to a request for information directed to the QIC that conducted the reconsideration or its successor (if a QIC contract has been awarded to a new contractor). In addition, we proposed to review § 405.1034(a) to include attorney adjudicators because attorney adjudicators would be authorized to adjudicate appeals, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). Also, while we proposed to retain the definition of “can be provided only by CMS or its contractors” in § 405.1034(a)(2), we proposed at § 405.1034(a)(1) to specify that official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. The redetermination and reconsideration are important documents that establish the issues on appeal, and while the parties often have copies of them, we stated in the proposed rule that we believed the record should include official copies from the contractors. In addition, we proposed at § 405.1034(b) to specify that the ALJ or attorney adjudicator would retain jurisdiction of the case, and the case would remain pending at OMHA. We proposed at § 423.2034(a) and (b) to adopt corresponding provisions for when information may be requested from an IRE and that jurisdiction is retained at OMHA in part 423, subpart U proceedings.

We proposed in § 405.1034(c) that the QIC would have 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the request for information, either directly or through CMS or another contractor. We stated that this would provide the ALJ or attorney adjudicator, the QIC, and the parties with a benchmark for obtaining the information and determining when adjudication of the case can resume. We proposed in § 405.1034(d) that, if an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period would be extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever is less. We stated that we recognize that other provisions that extend an applicable adjudication period generally involve an appellant's action or omission that delays adjudicating an appeal within an applicable time frame, but we stated in the proposed rule that we believed that an extension is also warranted to fully develop the record when the written record is missing information that is essential to resolving the issues on appeal, and that 20 calendar days (5 calendar days for the request to be received by the QIC and 15 calendar days for the QIC to respond) is a relatively modest delay in order to obtain missing information that is essential to resolving the appeal. We proposed at § 423.2034(c) and (d) to adopt corresponding provisions for the IRE to furnish the information or otherwise respond to the request for information, either directly or through CMS or the Part D plan sponsor, and the effect on any applicable adjudication time frame in part 423, subpart U proceedings. In addition, we proposed at § 423.2034(c) and (d) to provide for an accelerated response time frame for expedited appeals because of the urgency involved. For expedited appeals, we proposed that the IRE would have 2 calendar days after receiving a request for information to furnish the information or otherwise respond to the request, and the extension to the adjudication time frame would be up to 3 calendar days, to allow for time to transmit the request to the IRE and for the IRE to respond.

We proposed to add new § 405.1056 to describe when a request for hearing or request for review of a QIC dismissal may be remanded, and new § 405.1058 to describe the effect of a remand. We proposed in § 405.1056(a)(1) to permit a remand if an ALJ or attorney adjudicator

requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with proposed § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034. We also proposed in § 405.1056(a)(2) to permit a remand when the QIC does not furnish a case file for an appealed reconsideration. The remand under both provisions would direct the QIC or other contractor (such as a Medicare Administrative Contractor that made the redetermination) to reconstruct the record or initiate a new appeal adjudication. We stated in the proposed rule that we expected this type of remand to be very rare, but we also stated that we believed it was necessary to help ensure a complete administrative record of the administrative adjudication of a claim. To address the possibility that the QIC or another contractor is able to reconstruct the record for a remanded case, we proposed in § 405.1056(a)(3) to provide that in the situation where a record is reconstructed by the QIC, the reconstructed record would be returned to OMHA, the case would no longer be remanded and the reconsideration would no longer be vacated, and if an adjudication period applies to the case, the period would be extended by the time between the date of the remand and the date the case is returned to OMHA (because OMHA was unable to adjudicate the appeal between when it was remanded and when it was returned to OMHA). We stated that this would help ensure that appellants are not required to re-start the ALJ hearing or dismissal review process in the event that the QIC or another contractor is able to reconstruct the record. We proposed at § 423.2056(a) to adopt corresponding provisions for remanding cases in which there is a missing appeal determination or the IRE is unable to furnish the case file in part 423, subpart U proceedings.

On occasion, an ALJ finds that a QIC issued a reconsideration that addresses coverage or payment issues related to the appealed claim when a redetermination was required and no redetermination was conducted, or the contractor dismissed the request for redetermination and the appellant appealed the contractor's dismissal. We stated in the proposed rule that, in either circumstance, the reconsideration was issued in error because the appellant did not have a right to the reconsideration in accordance with current § 405.960, which only provides a right to a reconsideration when a redetermination is made by a contractor.

We stated that we do not believe that an administrative error made by the QIC conveys rights that are not afforded under the rules. We proposed in § 405.1056(b) to address these circumstances so that, if an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required) or the request for redetermination was dismissed (and not vacated), the reconsideration would be remanded to the QIC that issued the reconsideration, or its successor, to re-adjudicate the request for reconsideration. We again stated in the proposed rule that we expected this type of remand to be rare, but believed it was necessary to correct administrative errors in the adjudication process. We proposed at § 423.2056(b) to adopt a corresponding provision for when an IRE issues a reconsideration that addresses drug coverage when no redetermination was conducted or a request for redetermination was dismissed and is appealed to OMHA under part 423, subpart U.

OMHA ALJs sometimes receive requests for remands from CMS or a party because the matter can be resolved by a CMS contractor if jurisdiction of the claim is returned to the QIC. Current § 405.1034 does not address this type of request. We proposed at § 405.1056(c)(1) to provide a mechanism for these remands. Specifically, we proposed that at any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors, may jointly request a remand of the appeal to the entity that conducted the reconsideration. We proposed that the request include the reasons why the appeal should be remanded and indicate whether remanding the case would likely resolve the matter in dispute. Proposed § 405.1056(c)(2) would allow the ALJ or attorney adjudicator to determine whether to grant the request and issue the remand, based on his or her determination of whether remanding the case would likely resolve the matter in dispute. We stated that we believe this added flexibility would allow appellants and CMS and its contractors to expedite resolution of a disputed claim when there is agreement to do so. We proposed at § 423.2056(c) to adopt corresponding provisions for requested remands in part 423, subpart U proceedings.

Current § 405.1034(b) provides that if, consistent with current § 405.1004(b), the ALJ determines that a QIC's dismissal of a request for

reconsideration was in error, the case will be remanded to the QIC. We proposed at § 405.1056(d) to incorporate this provision and to adopt a corresponding provision in § 423.2056(d) to incorporate current § 423.2034(b)(1) for remanding cases in which an IRE's dismissal of a request for reconsideration was in error, in part 423, subpart U proceedings. In addition, we proposed at § 423.2056(e) to incorporate current § 423.2034(b)(2), which provides that if an enrollee wants evidence of a change in his or her condition to be considered in the appeal, the appeal would be remanded to the IRE for consideration of the evidence on the change in condition.

Current § 405.1034(c) provides that the ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), and provides that unless the appellant is entitled to such relief, the ALJ applies the LCD or NCD in place on the date the item or service was provided. We proposed to incorporate these provisions at § 405.1056(e). We did not propose any corresponding provision for § 423.2056 because there is not a similar current provision for part 423, subpart U proceedings.

As noted above, current § 405.1034 does not address providing a notice of remand. We proposed at § 405.1056(f) to provide that OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant to the proceedings or a party to the hearing. The notice would state that, as discussed below, there is a right to request that the Chief ALJ or a designee review the remand. We stated in the proposed rule that we believed this would help ensure that the parties and CMS and its contractors receive notice that the remand order has been issued. We proposed at § 423.2056(f) to adopt a corresponding provision for a notice of remand in part 423, subpart U proceedings, except that only the enrollee receives notice because only the enrollee is a party, and CMS, the IRE, and the Part D plan sponsor only receive notice if they requested to participate and the request was granted.

Stakeholders have recounted instances in which they believe a remand was not authorized by the regulations, but were unable to take any action to correct the perceived error because a remand is not an appealable action and current § 405.1034 does not provide a review mechanism. We stated

that we do not believe that remands should be made appealable actions, but recognize that stakeholders need a mechanism to address remands that they believe are not authorized by the regulation. We proposed in § 405.1056(g) to provide a mechanism to request a review of a remand by allowing a party or CMS, or one of its contractors, to file a request to review a remand with the Chief ALJ or a designee within 30 calendar days of receiving a notice of remand. If the Chief ALJ or designee determines that the remand is not authorized by § 405.1056, the remand order would be vacated. We also proposed that the determination on a request to review a remand order is binding and not subject to further review so adjudication of the appeal can proceed. We proposed at § 423.2056(g) to adopt a corresponding provision for reviewing a remand in part 423, subpart U proceedings.

Current § 405.1034 does not discuss the effect of a remand. We proposed at § 405.1058, similar to current §§ 405.1048 and 405.1054 which describe the effects of a decision and dismissal, respectively, that a remand of a request for hearing or request for review is binding unless it is vacated by the Chief ALJ or a designee in accordance with proposed § 405.1056(g). We stated in the proposed rule that we believed the provision would add clarity for the parties and other stakeholders on the effect of a remand order. We proposed at § 423.2058 to adopt a corresponding provision for the effect of a remand in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received one comment requesting clarification on why proposed §§ 405.1034(a)(1) and 423.2034(a)(1) require that official copies of redeterminations and reconsiderations that were conducted on the appealed issues can only be provided by CMS and its contractors or by CMS, the IRE, and/or the Part D Plan Sponsor, respectively, when the appellant can also furnish a copy of the same documents. The commenter believes that it is unnecessary and unfair to extend the adjudication period 15 days or more to obtain the "official copy."

*Response:* Because OMHA is tasked with compiling the official administrative record, it is necessary that OMHA obtain official versions of the redetermination decision and the reconsideration decision directly from the contractors if they are missing on appeal. These documents establish the

issues on appeal and are therefore important evidence in the administrative record. Although parties often have copies of these documents as well, copies may be altered or edited and there is no way to verify their authenticity unless they come directly from the contractor.

We do not believe that proposed §§ 405.1034(a)(1) and 423.2034(a)(1) place any unnecessary burden on the parties or that they will cause significant delays in the adjudication of appeals. First, we note that in many cases the lower level decisions are available on a CMS case processing system that is accessible to OMHA. If the missing lower level decision is uploaded to an official system of record (generally the case processing system used by the contractor and accessible to OMHA), then OMHA could accept that document as the official copy. In these cases, no information request would be necessary under §§ 405.1034(a) or 423.2034(a). We are modifying the language in §§ 405.1034(a)(1) and 423.2034(a)(1) to clarify that prior to submitting an information request, OMHA must first check the system of record to confirm whether a copy of the missing lower level decision is available there. In the extremely small number of cases where official copies were not provided in the record and were not uploaded by the contractor to the case processing system, then the ALJ or attorney adjudicator would use the proposed regulations to request an official copy of the missing lower level decision. In these cases, the adjudication period may be extended pursuant to §§ 405.1034(d) or 423.2034(d). However, given the ready availability of such evidence in the contractor's system, it should take minimal time for the contractor to produce the necessary documents, and we would anticipate that the extension also would be minimal.

*Comment:* One commenter expressed support for the sections in proposed § 405.1056 and § 405.1058 that describe when a request for hearing or a request for review of a QIC dismissal may be remanded and the effects of a remand. The commenter specifically appreciated the revisions that state that when a record has been reconstructed by the QIC on remand that it would be returned to OMHA, stating that this procedure helps ensure that appellants are not required to restart the whole review process. The commenter did have concerns, however, about proposed § 405.1056(b), which requires a remand where the QIC issued a reconsideration decision but no redetermination decision had been

made or the request for redetermination was dismissed, because the commenter felt that provision would result in the appellant unnecessarily having to start over at the first level of appeal. The commenter provided an example in which a redetermination decision was issued upholding a technical denial and then the appellant submitted evidence at the reconsideration level that cured the technical defect. In the example, the commenter argued that if the QIC proceeded to issue a reconsideration decision that addressed availability of coverage and payment issues and the reconsideration were appealed to OMHA, it would be a waste of time and resources for the ALJ or attorney adjudicator to remand the matter back to the QIC under § 405.1056(b) to have the QIC remand the case back to the Medicare administrative contractor for a redetermination decision addressing coverage and payment. The commenter requested additional examples of how § 405.1056(b) may impact appeals brought on behalf of Medicare beneficiaries and Medicaid State agencies.

*Response:* We thank the commenter for its support and agree that the proposals streamline the process for remands and will benefit appellants in instances when an appeal can be returned to the OMHA level of review without having to re-file an appeal, when the QIC or a contractor is able to reconstruct the record. We disagree, however, that proposed § 405.1056(b) would result in appellants having to re-file appeals unnecessarily or result in a waste of time and resources. Proposed § 405.1056(b) is intended to address two situations where a necessary redetermination was not issued but is required before the QIC can issue a reconsideration addressing coverage and payment issues. In the first situation, the contractor did not issue any redetermination. Pursuant to § 405.972(b)(6), the QIC must dismiss the reconsideration request in this situation and does not have authority to issue a reconsideration decision addressing coverage or payment issues. In the second situation, the contractor dismissed the redetermination request. Pursuant to § 405.974(b), a party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by the QIC. The QIC, however, does not have authority to issue a reconsideration decision addressing coverage and payment issues in this situation. As outlined in § 405.974(b)(2) and (3), the QIC may either determine that the dismissal was in error and vacate the dismissal and

remand the case to the contractor for a redetermination, or the QIC may affirm the dismissal as correct and the party is bound by that determination and has no further appeal review options. Because the QIC does not have authority to issue a reconsideration decision that addresses coverage and payment issues in either of the situations, if the QIC issues such a reconsideration decision it has done so in error. If the reconsideration decision was issued in error, the request for hearing must be remanded to the QIC pursuant to § 405.1056(b). Although we believe that this type of remand will be rare, we believe it is necessary to correct administrative errors in the adjudication process. We do not believe that an administrative error made by the QIC conveys rights that are not afforded under the rules and, therefore, believe that proposed § 405.1056(b) is a necessary revision.

We do not believe that proposed § 405.1056(b) would apply to the facts that were outlined in the commenter's example. In the example presented in the comment, the contractor did issue a redetermination, albeit a denial on technical grounds. The part 405, subpart I regulations do not make a distinction between redeterminations based on a technical denial and redeterminations based on other reasons, such as a denial because the item or service was not medically reasonable and necessary. Both redeterminations would give the party a right to request a QIC reconsideration on the coverage and payment issues. The party would then have a right to appeal the QIC's reconsideration for an ALJ hearing, provided the amount in controversy and other filing requirements were met, and the remand provisions of proposed § 405.1056(b) would not apply.

Further, proposed § 405.1056(b) applies to any request for hearing on a QIC reconsideration where the QIC issued a coverage and payment decision in error as discussed above. We do not believe there are any special considerations regarding the proposal that would apply differently based on the party appealing the claim, and therefore do not believe adding examples of how the proposal impacts an appeal filed by a beneficiary or a Medicaid State agency will be helpful.

*Comment:* The same commenter also had reservations about proposed § 405.1056(c), which would allow the appellant and CMS or its contractor to jointly request a remand to the QIC or IRE at any time before the ALJ or attorney adjudicator issues a decision or dismissal. The commenter suggested that such "joint request" would likely

be initiated and facilitated by CMS or its contractor and that those entities would have greater knowledge and bargaining power than appellants, especially appellants who are unrepresented beneficiaries. The commenter suggested that ALJs should be required to hold pre-hearing conferences to confirm both parties' understanding of the possible ramifications if the remand is granted and requested additional information on how beneficiaries' interests would be protected under § 405.1056(c).

*Response:* We disagree with the commenter that proposed § 405.1056(c) would operate to place appellants, including appellants who are unrepresented beneficiaries, into a disadvantaged position. Proposed § 405.1056(c) requires that any request for remand under this provision must be a joint request between the appellant and CMS or its contractors. We believe there is little incentive for an appellant to agree to a remand unless his or her claim will be paid in part or full or the resolution offered by CMS and its contractors on remand would be otherwise acceptable to the appellant, such as the review of new evidence in the appeal. We also see little advantage to CMS or its contractors in requesting remands unless they believe that they are able to effectively resolve a dispute in such a way that the resolution is mutually acceptable and the appellant will not appeal again. Although the commenter was concerned that appellants, and especially unrepresented beneficiaries, may have insufficient knowledge or bargaining power to protect themselves from entering joint remand requests that are not to their benefit, we believe that the requirements regarding a statement of the reasons for the remand, the likely resolution of the dispute, and the ALJ's or attorney adjudicator's review of these statements is a significant and sufficient safeguard. We believe that the adjudicator's review of the joint request and submitted statements will help ensure that the remand is truly jointly requested and that all individuals and entities involved are in agreement regarding the reasons for and likely resolutions of the remand. Although the commenter recommended a pre-hearing conference instead to determine that the parties understand the ramifications of a remand, we believe that requiring written reasons and a statement indicating whether the remand will likely resolve the matter in dispute is sufficient. Further, under proposed § 405.1056(c)(2), the ALJ or attorney adjudicator would have discretion in granting the remand request and may

only grant the request if he or she determines that remanding the case will likely resolve the matter in dispute. If the appellant is not going to be favorably treated on remand, then the appellant is likely to appeal the issue again to the OMHA level and the dispute will not be resolved. Therefore, the requested remands will only be granted where the likely resolution is favorable and/or unlikely to lead to subsequent appeal. We believe that proposed § 405.1056(c) provides a valuable tool to appellants that will allow expedited resolution of a disputed claim when there is agreement between the appellant and CMS and its contractors, and that the regulation contains sufficient safeguards to protect the appellants, including unrepresented beneficiaries.

*Comment:* We received one comment opposing the new review mechanisms for remand orders proposed in §§ 405.1056(g) and 423.2056(g). The commenter believes that these proposals result in an unprecedented authorization of power in the Chief ALJ or a designee to reverse the decisions of ALJs, and unnecessarily raise issues of ex parte communication and the appearance of impropriety. The commenter also suggested that the proposed review mechanism was problematic because the Chief ALJ's ability to delegate is not limited and the commenter believes the proposal conflicts with the APA concepts of an ALJ's qualified decisional independence and rotational assignment of appeals. The commenter stated that remands are rarely issued under the current rules, and recommended that a preferable alternative to the proposals would be to substantially limit the ALJs' remand authority.

*Response:* We proposed the review mechanisms in §§ 405.1056(g) and 423.2056(g) to give stakeholders, including appellants and CMS contractors, a means of recourse if an appeal is remanded and they believe the remand is outside of the scope of the remand regulations. As we state above, although we do not believe that remands should be made appealable actions, we believe some mechanism to challenge remands is necessary to be responsive to stakeholders who, in the past, believed that some remands were not authorized by the regulations and who felt that they did not have any way to address or correct the perceived error. Because a remand likely adds additional adjudication time and delay to the appeals process, we believe that providing a review mechanism to stakeholders is fair and will help ensure that remands that are outside of the

scope of the remand regulations do not derail appeals in error.

The review mechanisms proposed in §§ 405.1056(g) and 423.2056(g) also are intended to help ensure consistency in processing appeals. Previously, if an appeal was remanded to the QIC or IRE and that level of review did not agree that there was jurisdiction for the remand under current §§ 405.1034 or 423.2034, there was no clear guidance on how to proceed. Some QICs or IREs would reopen the previous decision while others would respond to the remand via a different mechanism. When ALJs issued remand orders outside of the scope of §§ 405.1034 or 423.2034, it created inconsistencies and confusion not only for CMS and its contractors regarding how to proceed, but also for appellants regarding the status and handling of their appeal. The proposed review mechanisms will help ensure that the procedural remand rules are applied in a consistent manner and that the processing of the remands at lower levels is also more uniform.

We limited the review authority to the Chief ALJ or a designee so that limited individuals within the agency will be tasked with this new review responsibility, which is a limited-scope review of a discrete procedural question. In this way, we believe that the requested reviews can be completed both consistently and efficiently. We added the ability for the Chief ALJ to designate other individuals to assist with the review of remands, if necessary, to ensure that there will be adequate resources to complete the reviews as expeditiously as possible, so the appeal can proceed as remanded, or with the ALJ.

We disagree with the commenter that the proposed review mechanisms may be used to reverse ALJ decisions or to override the qualified decisional independence that ALJs have when making decisions. We believe that remands are distinct from the decisions described in sections 554 and 556 of the APA because the permitted remands are generally procedural mechanisms that do not resolve the issues on appeal, but rather return the appeal to the second level of the appeals process without a resolution of the appealed matter. The one exception to this distinction is when the remand is issued on a request for review of a QIC's or IRE's dismissal of a request for reconsideration. In §§ 405.1056(d) and 423.2056(d) as finalized in this rule, an ALJ or attorney adjudicator issues a remand to the appropriate QIC or IRE if the ALJ or attorney adjudicator determines that the dismissal of a request for reconsideration was in error. We

recognize that remands issued on review of a QIC's or IRE's dismissal of a request for reconsideration are more akin to a determination than a purely procedural mechanism. Therefore, we are modifying the language in §§ 405.1056(g) and 423.2056(g) to specifically exempt remands that are issued under §§ 405.1056(d) and 423.2056(d) from potential review by the Chief ALJ or designee. The remaining remands, however, are issued on procedural grounds. We do not agree that creating a review mechanism for remands issued on procedural grounds impinges on an ALJ's qualified decisional independence with respect to his or her decisions. Further, we do not agree that the proposal interferes with rotational assignments of appeals because there is no right to an ALJ hearing when a request for review of an ALJ remand is made, thus the rotational assignment principle of 5 U.S.C 3105 does not apply.

We also do not agree with the commenter that this review mechanism will result in *ex parte* communications or the appearance of impropriety. *Ex parte* communications involve communications that are not on the record between an individual involved in the decisional process and an interested party outside of the agency about the merits of the proceedings. See 5 U.S.C. 557(d). The proposed review mechanisms in §§ 405.1056(g) and 423.2056(g) permit either a party or CMS, or one of its contractors, to file a request to review a remand within 30 calendar days of receiving the notice of remand, which would be made part of the record. The proposed regulation provides for the same procedure regardless of the entity or individual requesting the review.

Finally, with respect to the suggested alternative of substantially limiting the ALJs' remand authority, we disagree with the commenter that the stakeholders' concerns that prompted this proposal would be sufficiently addressed by that alternative. The current regulations already substantially limit the ALJs' authority to remand and yet there have been instances, despite those limitations, where stakeholders still felt that remands were issued that were not authorized by the regulations. In addition, §§ 405.1056 and 423.2056, as finalized in this rule, do not expand the ALJs' remand authority compared to the current remand regulations in §§ 405.1034 and 423.2034, but rather they set forth the limited circumstances in which a remand may be issued. Although §§ 405.1056 and 423.2056 list specific situations where a remand may be issued, these provisions are narrower

than the current provisions at §§ 405.1034 and 423.2034 because they do not include the general language at §§ 405.1034 and 423.2034 providing for a remand when the ALJ believes the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors. Instead, §§ 405.1034(a) and 423.2034(a), as finalized in this rule, require that the ALJ or attorney adjudicator first request that information from the QIC or IRE. Although the ALJ or attorney adjudicator may still remand a case under §§ 405.1056(a) and 423.2056(a) if the QIC or IRE fail to provide an official copy of a missing redetermination or reconsideration or fail to provide the case file after a request for information under §§ 405.1034(a) and 423.2034(a), the specific circumstances in which remands can occur have been narrowed as compared to the broader remand authority set forth in current §§ 405.1034 and 423.2034. Because remands are only available in limited and narrowly defined circumstances in §§ 405.1056 and 423.2056, we anticipated that the review mechanisms created by this proposal will be used infrequently. We agree with the commenter that remands are rarely used today and, therefore, believe that the use of the review mechanisms proposed in §§ 405.1056(g) and 423.2056(g) would be even rarer.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing §§ 405.1058 and 423.2058 as proposed without modification, and we are finalizing the changes to §§ 405.1034, 405.1056, 423.2034, and 423.2056 as proposed, with the following modifications. We are amending §§ 405.1034(a)(1) and 423.2034(a)(1) to provide that prior to issuing a request for information to the QIC or IRE, OMHA will confirm whether an electronic copy of the missing redetermination or reconsideration is available in the official system of record, and if so, will accept the electronic copy as an official copy. In addition, we are amending §§ 405.1056(g) and 423.2056(g) to add language to specifically exempt remands that are issued under §§ 405.1056(d) and 423.2056(d) (on a review of a QIC's or IRE's dismissal of a request for reconsideration) from potential review by the Chief ALJ or designee. Finally, we are replacing "can only be provided by CMS, the IRE, and/or the Part D plan sponsor" in proposed § 423.2034(a)(1), which was a drafting error, with "can be provided only by CMS, the IRE, and/or

the Part D plan sponsor," for consistency with the definition in § 423.2034(a)(2).

q. Description of the ALJ Hearing Process and Discovery (§§ 405.1036, 405.1037, and 423.2036)

As described below, we proposed a number of changes to §§ 405.1036 and 423.2036, which describe the ALJ hearing process, including the right to appear and present evidence, waiving the right to appear at the hearing, presenting written statements and oral arguments, waiver of the adjudication period, what evidence is admissible at the hearing, subpoenas, and witnesses at a hearing. 81 FR 43790, 43836–43837. Current § 405.1037 describes the discovery process in part 405, subpart I proceedings, which is permitted when CMS or a contractor elects to be a party to the ALJ hearing; there is no corresponding provision for part 423, subpart U proceedings because CMS, the IRE, and the Part D plan sponsor may not be made parties to the hearing.

Current § 405.1036(b)(1) states that a party may "send the ALJ" a written statement indicating that he or she does not wish to appear at the hearing. We proposed at § 405.1036(b)(1) to revise this provision to state that a party may "submit to OMHA" a written statement indicating that he or she does not wish to appear at the hearing. We stated in the proposed rule that while the written statement could still be sent to an ALJ who is assigned to a request for hearing, we proposed that the statement could be submitted to OMHA (for example, the statement could be submitted with the request for hearing), or to the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), after the request is assigned, to provide more flexibility and to accommodate situations where an ALJ or attorney adjudicator has not been assigned a request for hearing. We proposed at § 423.2036(b)(1) to adopt a corresponding revision for submitting a waiver of the right to appear in part 423, subpart U proceedings. In addition, we proposed at § 423.2036(b)(1)(ii) to revise the current requirement for the "ALJ hearing office" to document oral requests to require "OMHA" to document oral requests, to help ensure that applicability of the requirement is clear regardless of whether the oral request is received by an adjudicator in an OMHA field office after the appeal is assigned to an ALJ or attorney adjudicator, or the oral request is received in the OMHA central office before the appeal is assigned to an ALJ or attorney adjudicator.

As discussed in section III.A.3.h of the proposed rule and II.B.3.h of this final rule above, we proposed to move the provision for waiving the adjudication period from current § 405.1036(d) to proposed § 405.1016(d) because proposed § 405.1016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers. To accommodate moving current § 405.1036(d) to proposed § 405.1016(d), we proposed to re-designate current § 405.1036(g), which describes witnesses at the hearing, as § 405.1036(d), because it more logically follows the discussion of presenting witnesses and oral arguments in current § 405.1036(c). For the same reasons, we proposed to move the provisions at § 423.2036(d) to § 423.2016(c), and proposed at § 423.2036(d) to re-designate current § 423.2036(g) as § 423.2036(d) to describe witnesses at a hearing in part 423, subpart U proceedings.

Current § 405.1036(f) discusses subpoenas. Current § 405.1036(f)(5)(i) states that an ALJ ruling on a subpoena request is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). As discussed in section III.A.3.h.ii of the proposed rule and II.B.3.h.ii of this final rule above, we proposed to remove section § 405.1104 and relocate provisions dealing with escalation to the Council to § 405.1016. Because the process for requesting escalation to the Council is now described in proposed § 405.1016(e) and (f), we proposed at § 405.1036(f)(5)(i) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f). Current § 405.1036(f)(5)(ii) discusses CMS objections to a "discovery ruling" in the context of a paragraph on reviewability of subpoena rulings and current § 405.1037(e)(2)(i) separately addresses CMS objections to a discovery ruling. We proposed to revise § 405.1036(f)(5)(ii) to replace the current reference to a "discovery ruling" with "subpoena ruling" so it is consistent with the topic covered by § 405.1036(f). No corresponding revisions are necessary in § 423.2036(f) because there is no reference to a "discovery ruling."

Current § 405.1037(a)(1) provides that discovery is permissible only when CMS or its contractors elects to participate in an ALJ hearing as a party. We stated in the proposed rule that,

while the intent is generally clear, the use of "participate" is potentially confusing given that CMS or one of its contractors can elect to be a participant in the proceedings, including the hearing, in accordance with current and proposed § 405.1010, or elect to be a party to the hearing in accordance with current and proposed § 405.1012. We proposed to revise § 405.1037(a)(1) to state that discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with proposed § 405.1012. As noted above, there are no provisions for discovery in part 423, subpart U proceedings because CMS, the IRE, or the Part D plan sponsor are not permitted to be a party to the hearing.

Current § 405.1037(e)(1) states that an ALJ discovery ruling or disclosure ruling is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1100 (for Council review in general), § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). For the reasons discussed above with regard to similar proposed changes in § 405.1036, we proposed at § 405.1037(e)(1) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f).

Current § 405.1037(f) describes the effect of discovery on an adjudication time frame, and provides that the time frame is tolled until the discovery dispute is resolved. However, we stated in the propose rule that it does not clearly state when the effect on an adjudication time frame begins, and "discovery dispute" is not used elsewhere in the section. In addition, we stated that current § 405.1037(f) does not contemplate that an adjudication time frame may not apply (for example, when the adjudication time frame is waived in accordance with proposed § 405.1016(d)). Therefore, we proposed to revise § 405.1037(f) to state that if an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery. We stated in the proposed rule that we believed this revision would provide a clearer standard for how an adjudication period is affected by discovery proceedings.

We received no comments on these proposals, other than comments

discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1036, 405.1037, and 423.2036 as proposed without modification.

r. Deciding a Case Without a Hearing Before an ALJ (§§ 405.1038 and 423.2038)

As described below, we proposed several changes to §§ 405.1038 and 423.2038, concerning when a case may be decided without a hearing before an ALJ. 81 FR 43790, 43837–43838. Current § 405.1038(a) provides authority to issue a "wholly favorable" decision without a hearing before an ALJ and without giving the parties prior notice when the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue. We proposed in § 405.1038 that if the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. Proposed § 405.1038(a) would replace "wholly favorable" with "fully favorable" in the subsection heading to align with language in § 405.1000(g), which addresses a fully favorable decision being made on the record, and the nomenclature used in OMHA's day to day operations. Proposed § 405.1038(a) would also replace "hearing record" with "administrative record" for consistency with other references to the record, and replace "hearing decision" with "decision," for consistency with other references to a decision. We proposed at § 423.2038(a) to adopt corresponding revisions to align with language in § 423.2000(g) and to make references to the record and decisions consistent in part 423, subpart U proceedings.

Proposed § 405.1038(a) would also add two new limitations on issuing a decision without a hearing before an ALJ when the evidence in the administrative record supports a finding in favor of the appellant(s) on every



issue. First, a decision could not be issued pursuant to proposed § 405.1038(a) if another party to the appeal is liable for the claims at issue. Second, a decision could not be issued pursuant to proposed § 405.1038(a) if CMS or a contractor elected to be a party to the hearing in accordance with § 405.1012. We stated in the proposed rule that we recognized that this may limit decisions that may be issued pursuant to § 405.1038(a); however, we also stated that we believed only a small number of appeals would be affected, and the new limitations would mitigate the impact of such a decision on the other parties to the appeal and the likelihood of an appeal to, and remand from, the Council. No corresponding changes were proposed in § 423.2038(a) because only the enrollee is a party in part 423, subpart U proceedings.

Current § 405.1038(b)(1) permits the ALJ to decide a case on the record and not conduct a hearing if: (1) All the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or (2) an appellant lives outside of the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear. We proposed to retain this structure in proposed § 405.1038(b) but did propose some changes. Current § 405.1038(b)(1)(i) requires all parties to indicate in writing that they do not wish to appear before the ALJ at a hearing, and as indicated above, current § 405.1038(b)(1)(ii) is contingent on no other parties wishing to appeal. However, the requirement to obtain a writing from all parties or determine the wishes of the non-appellant parties has limited the utility of the provisions. While all parties have a right to appear at the hearing, a notice of hearing is not sent to parties who did not participate in the reconsideration and were not found liable for the items or services at issue after the initial determination, in accordance with current § 405.1020(c). We proposed at § 405.1038(b)(1)(i) and (b)(1)(ii) to modify the requirements so writings only need to be obtained from, or wishes assessed from, parties who would be sent a notice of hearing, if a hearing were to be conducted. We stated that using the notice of hearing standard protects the interests of potentially liable parties, while making the provisions a more effective option for the efficient adjudication of appeals. In addition, proposed § 405.1038(b)(1) would reinforce that only an ALJ conducts a hearing by indicating an ALJ

or attorney adjudicator may decide a case on the record without an ALJ conducting a hearing. Proposed § 405.1038(b)(1)(ii) also would indicate that an appellant who lives outside of the United States would inform “OMHA” rather than “the ALJ” that he or she wants to appear at a hearing before an ALJ, so an appellant could make that indication before an appeal is assigned to an ALJ or attorney adjudicator. We proposed at § 423.2038(b)(1) and (b)(1)(ii) to adopt corresponding revisions to reinforce that only an ALJ conducts a hearing and an enrollee who lives outside of the United States would inform OMHA that he or she wishes to appear at a hearing before an ALJ, but the other changes in proposed § 405.1038(b) were not proposed in § 423.2038(b) because only the enrollee is a party in part 423, subpart U proceedings. We also proposed in § 405.1038(b)(1)(i) to replace “videoteleconferencing,” and in § 423.2038(b)(1)(i) to replace “video teleconferencing,” with “video-teleconferencing,” for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020, and 423.2036.

On occasion, CMS or one of its contractors indicates that it believes an item or service should be covered or payment made on an appealed claim, either before or at a hearing. However, there are no current provisions that address this circumstance, and we stated in the proposed rule that it is one that is ideal for a summary decision in favor of the parties based on the statement by CMS or its contractor, in lieu of a full decision that includes findings of fact, conclusions of law, and other decision requirements. We proposed to add § 405.1038(c) to provide a new authority for a stipulated decision, when CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or paid. In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision. We proposed at § 423.2038(c) to adopt a corresponding authority for stipulated decisions in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received ten comments on the proposed limitations to issuing a decision without a hearing before an ALJ when the evidence in the

administrative record supports a finding in favor of the appellant(s) on every issue. Six commenters opposed adding that a decision cannot be issued pursuant to proposed § 405.1038(a) if CMS or a contractor elects to be a party to the hearing in accordance with § 405.1012. The commenters stated that the position of CMS and its contractors will be well established in the administrative record by the time the appeal reaches OMHA, and the record will contain all of the information available to the contractor at the time of its determination. The commenters stated that CMS and its contractors should not be allowed to delay the ALJ’s or attorney adjudicator’s decision if the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. Two of the commenters stated that this limitation could result in CMS contractors electing party status to force a hearing even when the record supports a fully favorable decision.

*Response:* As discussed above, we believe only a small number of appeals will be affected by the limitation in proposed § 405.1038(a) on issuing fully favorable decisions without a hearing before an ALJ when CMS or its contractor has elected to be a party to the hearing in accordance with § 405.1012. In accordance with proposed § 405.1012(a)(1), CMS or a contractor cannot elect to be a party to a hearing if the request for hearing was filed by an unrepresented beneficiary. Further, CMS or a contractor can only elect to be a party to a hearing in response to the notice of hearing pursuant to § 405.1012(b), or at the ALJ’s request. Currently, very few decisions are issued under § 405.1038(a) after a hearing is scheduled and the notice of hearing is sent to the parties and potential parties and participants. We expect that to continue to be true, but under current § 405.1038(a) there have been occasions when an ALJ has issued a decision in an appellant’s favor without conducting a hearing, after a hearing has been scheduled and CMS or its contractor has elected to be a party to the hearing.

If CMS or its contractor has properly elected to be a party, it has a right to appear at an ALJ hearing. As the claims payor, CMS and its contractors have an interest in the outcome of the case, similar to any other party to the appeal that is or may be liable for the claims at issue. Regardless of whether CMS’s position may be apparent from the administrative record by the time an appeal reaches the OMHA level, CMS or a contractor that has properly elected party status has the right to present its

arguments before the ALJ at the hearing. That right continues even if a fully favorable decision is issued under § 405.1038(a) as finalized in this rule, which provides that the notice of decision informs the parties that they have a right to a hearing. Thus, issuing a decision in the appellant's favor after CMS or its contractor has elected to be a party and without conducting the scheduled hearing would be an appealable issue to the Council and possibly result in a remand to OMHA to conduct the hearing, resulting in wasted resources at the Council to process the appeal and remand, and further delaying finality of the appeal for the parties. We do not agree that the proposal will result in CMS or its contractors electing party status to "force a hearing" because a hearing would already have to be scheduled for CMS or its contractors to elect party status. As noted above, very few decisions are currently issued under § 405.1038(a) after a hearing has been scheduled and CMS and its contractors have had the opportunity to elect party status. Therefore, we do not believe that § 405.1038(a), as finalized in this rule, will create a significant incentive for CMS or its contractors to elect party status just to force a hearing in those few cases where a decision might otherwise be issued on the record after a hearing has been scheduled. For the reasons discussed above, we believe that limiting decisions that can be issued under proposed § 405.1038(a) when CMS or a contractor has elected to be a party will only affect a small number of cases, and will reduce the number of those cases that are appealed to, and remanded from, the Council.

*Comment:* Two commenters stated that limiting decisions that can be made without a hearing will weaken the effectiveness of attorney adjudicators by reducing the number of appeals they can decide.

*Response:* We do not agree that this proposal will weaken the effectiveness of attorney adjudicators. As noted above, these limitations will not affect a significant number of cases and will prevent attorney adjudicators from making decisions that would likely be subject to appeal to the Council by non-appellant parties seeking their right to a hearing, and possible remand back to OMHA for an ALJ to conduct the hearing.

*Comment:* One commenter suggested clarifying the procedure for transferring a case from an ALJ to an attorney adjudicator when the case is appropriate for a decision without conducting a hearing.

*Response:* As discussed in section II.A.2 above, OMHA's business practice is to assign appeals to ALJs in rotation so far as practicable, and appeals will be assigned to attorney adjudicators in the same manner. If an appeal is initially assigned to an ALJ but is deemed appropriate for a decision by an attorney adjudicator, the appeal would be reassigned to an attorney adjudicator in the same manner as a new appeal assignment to an attorney adjudicator. More information on the appeal assignment process is available in the OCPM, which is accessible to the public at the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)).

*Comment:* One commenter requested clarification regarding the time frame for requesting a hearing after a fully favorable decision is issued pursuant to § 405.1038(a) or § 423.2038(a), as the regulation states the parties have the right to a hearing but is silent regarding the time frame for requesting a hearing.

*Response:* The language in proposed §§ 405.1038(a) and 423.2038(a) stating that the parties have the right to a hearing is carried over from current §§ 405.1038(a) and 423.2038(a). As discussed in section II.A.2 above, parties to an appeal that is decided without a hearing may pursue their right to a hearing by requesting a review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. The request for review by the Council must be filed in accordance with proposed §§ 405.1102 and 423.2102.

*Comment:* One commenter stated that an ALJ should be allowed to issue a decision that is fully favorable to the appellant without conducting a hearing even if another party is liable for the claims at issue, as long as the party that is liable for the claims at issue waives its right to appear at a hearing.

*Response:* If all of the parties who would be sent a notice of hearing, which under proposed § 405.1020(c)(1) would include, among others, the appellant and any other party who is or may be liable for the claims at issue, indicate in writing that they do not wish to appear at a hearing, an ALJ or attorney adjudicator may decide a case on the record pursuant to § 405.1038(b).

*Comment:* Two commenters stated that if an appellant waives the right to a hearing before an ALJ under §§ 405.1038 and 405.1020, and the case is decided by an attorney adjudicator rather than an ALJ, the administrative record must demonstrate that the waiver was valid and informed. One commenter expressed concern that appellants may be motivated to waive a hearing in order to avoid the delay of

waiting for an ALJ hearing, and stated that appellants should be assured that a decision will generally be made by an ALJ or attorney adjudicator in the same time frame.

*Response:* As finalized in this rule, §§ 405.1038(b) and 405.1020(d) provide that a decision may be issued by an attorney adjudicator or an ALJ if all the parties that would be sent a notice of hearing in accordance with § 405.1020(c) waive a hearing before an ALJ in writing. Publication of this final rule will inform appellants of the possibility that an attorney adjudicator may decide a case if the parties waive the right to a hearing. Accordingly, we do not believe that any further documentation of a party's understanding is necessary to demonstrate a valid waiver. However, we will review the current optional HHS form for waiving an ALJ hearing (Form HHS-723, Waiver of Right to an Administrative Law Judge (ALJ) Hearing), and consider making changes to reinforce this provision of the rule for those who choose to use that form.

ALJs and attorney adjudicators will be subject to the same time frames for issuing a decision, dismissal, or remand, as discussed in section II.B.3.h above, including when decisions are issued under §§ 405.1038(b) and 423.2038(b) as finalized in this rule. However, we note that if all of the parties waive a hearing and a decision can be issued pursuant to § 405.1038(b) or § 423.2038(b) without conducting a hearing, the decision may be issued sooner than if a hearing were scheduled and conducted, regardless of whether an ALJ or attorney adjudicator issues the decision under § 405.1038(b) or § 423.2038(b). Scheduling a hearing requires the ALJ to determine an available hearing date and time and give the parties sufficient advance notice (at least 20 calendar days under § 405.1022(a) and for non-expedited Part D hearings under § 423.2022(a)). Sections 405.1020(e)(4) and 423.2020(e)(4) allow for hearings to be rescheduled if a party or the enrollee objects to the scheduled date and/or time and the ALJ finds good cause to reschedule the hearing, which could result in even longer delays. Appellants who wish to avoid the additional time it takes to schedule and conduct a hearing before a decision can be issued may choose to waive the hearing.

*Comment:* Three commenters strongly supported our proposal to allow stipulated decisions in favor of the parties based on a statement by CMS or its contractor that an item or service should be covered or payment made on an appealed claim. One commenter questioned whether there may be

circumstances in which it may be in a party's interest to obtain a full decision with findings of fact or conclusions of law regarding a specific policy, eligibility, or coverage issue, instead of a stipulated decision.

*Response:* We thank the commenters for their support. If CMS or its contractor agrees that an item or service should be covered or payment made on an appealed claim and an ALJ or attorney adjudicator issues a decision in accordance with proposed § 405.1038(c), we do not believe that the decision will be detrimental to the parties' interests given that an ALJ's or attorney adjudicator's decision is limited to the appealed claims and binding only on the parties to the appeal, and is not precedential. However, we note that proposed § 405.1038(c) does not require the ALJ or attorney adjudicator to issue a stipulated decision, but rather makes it an option. If a party believes that it has an interest in a full decision that includes findings of fact, conclusions of law, and the reasons for the decision, the party could express its desire for a full decision to the ALJ during the hearing if CMS or the contractor makes an oral statement at the hearing; to the assigned ALJ or attorney adjudicator if CMS or the contractor files a written statement and provides a copy to the parties; or in a request for review to the Council if a stipulated decision has already been issued.

*Comment:* One commenter stated that it would be insufficient to issue a stipulated decision based on a statement from CMS that the item or service would be covered, without first disclosing the amount of payment that would be made on the claim and allowing the appellant to accept or reject the payment, because often the amounts paid by CMS contractors for certain items of durable medical equipment do not accurately reflect the cost of the items.

*Response:* We do not believe adding a requirement for all cases in which a stipulated decision may be issued that CMS disclose the amount of payment that would be made, and that the appellant be allowed to accept or reject the payment before a stipulated decision could be issued, would be necessary, and we believe it would waste resources and negate the intended efficiency of the proposal when CMS or a contractor believes an item or service should be covered or payment may be made. Section 405.1046(a)(3), as finalized in this rule, incorporates current § 405.1046(c), which provides that an ALJ or attorney adjudicator may make a finding as to the amount of payment due

for an item or service when the payment amount is at issue. However, under these regulations, such a finding is not binding on a CMS contractor for purposes of determining the amount of payment due and the amount of payment determined by the contractor in effectuating an ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924, which may be appealed. These rules would apply to a stipulated decision, and as such, if a payment amount is included in a stipulated decision, it does not guarantee that amount will be paid. Further, allowing an appellant to veto a stipulated decision by rejecting the payment that would be made on the claim would require the ALJ or attorney adjudicator to issue a full decision, including findings of fact, and conclusions of law, and comply with other decision requirements in § 405.1046, which would be subject to the same limitations of proposed § 405.1046(a)(3) regarding payment amounts.

However, we agree that it would not be appropriate for an ALJ or attorney adjudicator to issue a stipulated decision when the amount of payment is specifically at issue before the ALJ or attorney adjudicator, if the statement from CMS or its contractor does not agree to the amount of payment the party believes should be made. If the amount of payment on a claim is at issue before the ALJ or attorney adjudicator, a general statement from CMS or its contractor that the item or service should be covered or payment may be made would not address the issue on appeal. We are therefore amending § 405.1038(c) to provide that if the amount of payment is an issue before the ALJ or attorney adjudicator, a stipulated decision may be made if the statement from CMS or its contractor agrees to the amount of payment the party believes should be made. We are making a corresponding change to § 423.2038(c) for stipulated decisions in part 423, subpart U proceedings.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1038 and 423.2038 as proposed with the following modification. We are amending §§ 405.1038(c) and 423.2038(c) to provide that if the amount of payment is an issue before an ALJ or attorney adjudicator, the statement upon which a stipulated decision is based must agree to the amount of payment the parties believe should be made.

s. Prehearing and Posthearing Conferences (§§ 405.1040 and 423.2040)

As described below, we proposed a number of changes to §§ 405.1040 and 423.2040 with respect to prehearing and posthearing conferences. 81 FR 43790, 43838–43839. Current § 405.1040 discusses prehearing and posthearing conferences and permits the ALJ to hold these conferences to facilitate the hearing or hearing decision. Current § 405.1040(b) requires an ALJ to inform "the parties" of the time, place, and purpose of the prehearing or posthearing conference, unless a party indicates in writing that it does not wish to receive a written notice of the conference. In accordance with current § 405.1020(c), the notice of hearing is not sent to a party who did not participate in the reconsideration and was not found liable for the services at issue after the initial determination. Therefore, we proposed to modify § 405.1040(b) to state that the ALJ would inform parties who would be or were sent a notice of hearing in accordance with § 405.1020(c). In addition, current § 405.1040(b) does not provide for conference notice to be sent to CMS or a contractor that elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent, which has caused confusion when CMS or a contractor has made an election before or after a conference. Therefore, we proposed at § 405.1040(b) that a conference notice be sent to CMS or a contractor that has elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent. We stated in the proposed rule that we believed these changes would help ensure the appropriate parties and participants are provided with notice of, and have an opportunity to attend, a conference. We proposed at § 423.2040(b) and (c) to adopt corresponding revisions for prehearing conference notices in non-expedited and expedited hearings respectively to state that a conference notice is sent to CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant in the hearing, but we did not propose to make other changes in proposed § 405.1040(b) to § 423.2040 because only the enrollee is a party in part 423, subpart U proceedings. In addition, because an oral request not to receive a notice of the conference is permitted for expedited hearings, we proposed at § 423.2040(d) to revise the requirement for an "ALJ hearing office" to document such an oral request to provide more generally that oral requests must be documented,

which is generally done by the ALJ's support staff, rather than other office staff. In addition, we proposed at § 423.2040(d) that documentation of an oral request not to receive written notice of the conference must be added to the administrative record for consistency in how the record is referenced.

Current § 405.1040(c) states that, at the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. However, OMHA ALJs have indicated that providing them with the discretion to delegate conducting a conference to an attorney would add efficiency to the process. OMHA attorneys are licensed attorneys who support ALJs in evaluating appeals and preparing appeals for hearing, as well as drafting decisions, and are well versed in Medicare coverage and payment policy, as well as administrative procedure. Therefore, we proposed at § 405.1040(c)(1) that, at the conference, the ALJ or an OMHA attorney designated by the ALJ may conduct the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing. We stated in the proposed rule that this revision would allow an OMHA attorney designated by the ALJ assigned to an appeal to conduct a conference, but would only allow an ALJ conducting the conference to consider matters in addition to those stated in the conference notice. We stated that we believe allowing ALJs to delegate the task of conducting a conference (consistent with the conference notice stating the purpose of the conference, in accordance with § 405.1040(b)) would provide ALJs with the flexibility to use OMHA attorneys and provide ALJs with more time to devote to hearings and decisions. We also stated that we believe using attorneys to conduct conferences is appropriate because conferences are informal proceedings to facilitate a hearing or decision, and do not involve taking testimony or receiving evidence, both of which occur at the hearing. We also noted that the results of the conference embodied in a conference order are subject to review and approval by the ALJ, and ultimately subject to an objection by the parties, under the provisions of current § 405.1040, which are carried over in proposed § 405.1040. We proposed at § 423.2040(e)(1) to adopt corresponding revisions for allowing an ALJ to delegate conducting a conference to an OMHA attorney in part 423, subpart U proceedings.

Current § 405.1040(c) references the notice of hearing in discussing the matters that are considered at a conference. However, a notice of hearing may not have been issued at the time a prehearing conference is scheduled, and the matters being addressed in the appeal may have evolved since a notice of hearing was issued by the time a posthearing conference is scheduled, resulting in confusion on the permissible scope of the matters discussed at a conference. Therefore, § 405.1040(c)(1) would state that the matters that are considered at a conference are those stated in the conference notice (that is, the purpose of the conference, as discussed in current § 405.1040(b)).

Current § 405.1040(c) states that a record of the conference is made. However, that requirement has been read and applied differently by adjudicators. We proposed at § 405.1040(c)(2) to require that an audio recording of the conference be made to establish a consistent standard and because the audio recording is the most administratively efficient way to make a record of the conference. We proposed at § 423.2040(e)(1) and (e)(2) to adopt corresponding revisions to reference a conference notice and clarify that an audio recording of the conference is made in part 423, subpart U proceedings.

Current § 405.1040(d) requires the ALJ to issue an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties. It does not state to whom a conference order is issued, and again broadly references parties in indicating who may object to the order. In addition, current § 405.1040(d) does not establish a time period within which an objection must be made before the order becomes part of the record and binding on the parties. Therefore, we proposed to revise § 405.1040(d) to state that the ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. We proposed that if a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties. Proposed § 405.1040(d) would provide that the order is issued to the parties and participants who attended the conference to help ensure the appropriate parties and participants receive the order, but as in current § 405.1040(d), only a party could object

to the order. Proposed § 405.1040(d) would also establish that an objection must be made within 10 calendar days of receiving the order to establish a consistent minimum standard for making an objection to a conference order, but would also provide the ALJ with the discretion to grant additional time. In addition, proposed § 405.1040(d) would replace "hearing record" with "administrative record" for consistency with other references to the record. Further, proposed § 405.1040(d) would continue to only allow the ALJ to issue a conference order, because we believe the ALJ should review and approve the actions and agreements resulting from the conference, and only an ALJ should issue an order that would be binding on the parties, if no objection is made. We proposed at § 423.2040(f) to adopt corresponding revisions to clarify to whom a conference order is sent and the time frame to object to the order, and to specify that agreements and actions resulting from the conference become part of the "administrative record" (rather than "hearing record") in part 423, subpart U proceedings. However, we proposed to add that an enrollee must object to a conference order within 1 calendar day of receiving the order for expedited hearings because of the abbreviated time frame under which an expedited hearing and decision must be completed.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter stated that audio recordings, while administratively efficient, may be incompatible with a party's playback equipment, and transcription costs are prohibitively expensive. The commenter recommended that the format and medium of the recorded file be restricted and a typed transcript be provided on request if the file is incompatible with a party's equipment.

*Response:* While we acknowledge that there may be playback compatibility concerns when dealing with any digital medium, we do not believe that it would be appropriate to constrain the audio recording of the oral proceedings to a particular format by regulation. OMHA makes audio recordings of conferences and hearings using electronic audio file formats that can be played using widely available and free software. If a party is unable to play the audio recording using his or her own equipment, OMHA will work with the party to help ensure that he or she has adequate access to the administrative record, and possibly provide the recording in a different format.

However, we believe that this process is more appropriate for sub-regulatory guidance and the audio recordings should not be restricted to a specific format by regulation, as technology standards and software changes rapidly. We believe that the more general reference to audio recordings will accommodate future changes in recording formats and allow for more flexibility in responding to appellants' requests.

*Comment:* Another commenter questioned whether it was an acceptable practice for an ALJ to substitute a prehearing conference for a full hearing as long as the other parties had already waived their appearances, no taking of testimony or receiving of additional evidence was required, only argument would be presented, and the conference was being recorded. The commenter expressed concern that this approach may catch unrepresented beneficiaries unprepared, and suggested publishing a handbook or other guidance for beneficiaries on what to expect at a conference.

*Response:* The purpose of a prehearing conference is to facilitate the hearing and it is not a substitute for a full hearing. If, after conducting a prehearing conference, the ALJ determines that a hearing is no longer necessary because a decision can be issued without conducting a hearing in accordance with §§ 405.1038 or 423.2038, the ALJ may issue the decision on the record without conducting a subsequent hearing, or may issue a dismissal or remand in accordance with applicable authorities. However, a prehearing conference is not a substitute for a full ALJ hearing and the rules do not provide for taking testimony or evidence at a conference, or for the ALJ to fully examine the issues and to question the parties and witnesses, as is done at a hearing in accordance with §§ 405.1030 and 423.2030. In addition, we note that the notice of a pre-hearing conference does not contain the same information as a notice of hearing, and does not have to be sent in the same time frame. With respect to what an appellant can expect at the conference, proposed §§ 405.1040(b) and 423.2040(b) provide that a conference notice will explain the matters to be discussed at the conference. There are also a number of resources available to provide beneficiaries with information and guidance regarding what to expect throughout the appeals process, as discussed in section II.B.3.o of this final rule above, including existing CMS resources like the Medicare & You Handbook, 1–800 Medicare, chapter 29

of the Medicare Claims Processing Manual (Internet-Only Manual 100–4), and the Medicare claims appeals Web site at [www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html](http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html). OMHA is also currently in the process of developing and releasing the OCPM. The OCPM provides day-to-day operating instructions, policies, and procedures based on statutes, regulations, and OMHA directives. Development is ongoing, and although the OCPM is primarily intended to be a resource used by OMHA adjudicators and staff, chapters are made publicly available on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)) soon after they are published. The instructions and guidance in the OCPM describe many policies and procedures in greater detail and provide frequent examples to aid understanding. We plan to address prehearing and posthearing conference procedures in a future OCPM chapter.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1040 and 423.2040 as proposed without modification.

#### t. The Administrative Record (§§ 405.1042 and 423.2042)

The administrative record is HHS's record of the administrative proceedings, and is initially established by OMHA ALJs and built from the records of CMS contractors that adjudicated the claim, or from records maintained by SSA in certain circumstances. After adjudication by OMHA, the Council may include more documents in the administrative record, if a request for Council review is filed or a referral to the Council is made. If a party then seeks judicial review, the administrative record is certified and presented to the Court as the official agency record of the administrative proceedings. The record is returned to the custody of CMS contractors or SSA after any administrative and judicial review is complete. We stated in the proposed rule that current practices in creating the administrative record in accordance with current §§ 405.1042 and 423.2042 vary widely. Given the importance of the administrative record, we proposed to revise §§ 405.1042 and 423.2042 to provide for more consistency and to clarify its contents and other administrative matters. 81 FR 43790, 43839–43841.

Current § 405.1042(a)(1) provides that the ALJ makes a complete record of the evidence, including the hearing proceedings, if any. However, we stated in the proposed rule that this provision has been limiting and causes confusion

in developing procedures to ensure the completeness of the record and in bringing consistency to how the record is structured because individual adjudicators organize the record differently. We proposed to revise § 405.1042(a)(1) to require OMHA to make a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted. Proposed § 405.1042(a)(1) would vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter, including any prehearing and posthearing conferences and hearing proceedings. We stated that this would provide OMHA with more discretion to develop policies and uniform procedures for constructing the administrative record, while preserving the role of the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to identify the evidence that was used in making the determinations below and the evidence that was used in making his or her decision. We proposed at § 423.2042(a)(1) to also adopt corresponding revisions to indicate OMHA makes a complete record of the evidence and administrative proceedings in the appealed matter in part 423, subpart U proceedings.

Current § 405.1042(a)(2) discusses which documents in the record are marked as exhibits, and provides a non-exhaustive list of documents that are marked to indicate that they were considered in making the decisions under review or the ALJ's decision. It further states that in the record, the ALJ also must discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. We proposed to revise § 405.1042(a)(2) to state that the record would include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney admits. We proposed that attorney adjudicators could mark exhibits because as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), attorney adjudicators would be adjudicating requests for hearing and requests for review of a QIC dismissal,

and should indicate the portions of the record that he or she considered in making the decision in the same manner as an ALJ. Proposed § 405.1042(a)(2) would continue to require certain evidence to be marked as exhibits, but would clarify what would be marked, replacing “the documents used in making the decision under review,” with “the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ’s or attorney adjudicator’s decision.” We stated in the proposed rule that we believed this would clarify that the exhibited portion of the record includes, at minimum, the appealed determinations, documents and other evidence used in making the appealed determinations, and documents and other evidence used in making the ALJ’s or attorney adjudicator’s decision. The illustrative list of documents that may be marked as exhibits pursuant to the rule in current § 405.1042(a)(2) would be incorporated in proposed § 405.1042(a)(2) without change. We also proposed to clarify at § 405.1042(a)(2) that the record would include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party. We stated in the proposed rule that all evidence presented should be included in the record, even if excluded from consideration, in order to help ensure a complete record of the evidence. However, we stated that such excluded evidence would not be marked as an exhibit because the evidence was not considered in making the ALJ’s or attorney adjudicator’s decision. We proposed at § 423.2042(a)(2) to adopt corresponding revisions to clarify what would be exhibited in part 423, subpart U proceedings, except the reference to new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established as an example of evidence excluded or not considered by the ALJ or attorney adjudicator, because there is no such limitation on new evidence in part 423, subpart U proceedings.

As stated previously, current § 405.1042(a)(2) includes requirements to discuss any evidence excluded under current § 405.1028 and include a justification for excluding the evidence. We proposed in § 405.1042(a)(2) to remove these requirements. We stated in

the proposed rule that we believed the requirement to justify excluding the evidence is not necessary and is in tension with the requirement for a provider or supplier, or beneficiary represented by a provider or supplier, to establish good cause for submitting new evidence before it may be considered. Section 1869(b)(3) of the Act establishes a general prohibition on new evidence that must be overcome, and proposed § 405.1028 would implement the statute by requiring the party to explain why the evidence was not submitted prior to the QIC reconsideration, and the ALJ or attorney adjudicator to make a finding of good cause to admit the evidence. In place of the current § 405.1042(a)(2) requirement, as we discuss later, we proposed at § 405.1046(a)(2)(ii) to require that if new evidence is submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed § 405.1028, the new evidence and good cause determination would be discussed in the decision. We also stated in the proposed rule that we believed the decision is the appropriate place to discuss the new evidence and document the good cause determination, and the discussion should focus on the good cause determination required by proposed § 405.1028, regardless of whether good cause was found. We did not propose any corresponding changes to § 423.2042 because there is no provision equivalent to the current § 405.1042(a)(2) requirement to discuss any excluded evidence.

Current § 405.1042(a)(3) provides that a party may review the record “at the hearing,” or if a hearing is not held, at any time before the ALJ’s notice of decision is issued. However, this is rarely done in practice. More often, a party requests a copy of the record prior to the hearing, in accordance with current § 405.1042(b). We proposed to revise § 405.1042(a)(3) to state that a party may request and review the record prior to or at the hearing, or if a hearing is not held, at any time before the notice of decision is issued. This revision would allow a party to request and review a copy of the record “prior to or at the hearing” to more accurately reflect the practices of parties. In addition, proposed § 405.1042(a)(3) would remove the reference to an “ALJ’s” decision in explaining that if a hearing is not held, a party may request and review the record at any time before the notice of decision is issued, because in that circumstance an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above),

may issue the decision. We proposed at § 423.2042(a)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042(a)(4) provides for the complete record, including any recording of the hearing, to be forwarded to the Council when a request for review is filed or the case is escalated to the Council. However, in noting that the record includes recordings, only a recording of the hearing is mentioned. We proposed at § 405.1042(a)(4) to add that the record includes recordings of prehearing and posthearing conferences in addition to the hearing recordings, to reinforce that recordings of conferences are part of the complete record. We proposed at § 423.2042(a)(4) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042(b)(1) describes how a party may request and receive copies of the record from the ALJ. However, after a case is adjudicated, OMHA releases custody of the record and forwards it to a CMS contractor or SSA, and the record may go on to the Council for another administrative proceeding. We stated in the proposed rule that this results in confusion for parties when they request a copy of the record and OMHA is unable to provide it. We proposed at § 405.1042(b)(1) that a party may request and receive a copy of the record from OMHA while an appeal is pending at OMHA. We also proposed at § 405.1042(b)(1) to replace the reference to an “exhibit list” with a reference to “any index of the administrative record” to provide greater flexibility in developing a consistent structure for the administrative record. We also proposed to change the parallel reference to “the exhibits list” in § 405.1118 to “any index of the administrative record.” In addition, proposed § 405.1042(b)(1) would replace the reference to a “tape” of the oral proceeding with an “audio recording” of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We also proposed to replace a parallel reference at § 405.1118 to a copy of the “tape” of the oral proceedings with a copy of the “audio recording” of the oral proceedings. We proposed at §§ 423.2042(b)(1) and 423.2118 to adopt corresponding revisions for part 423, subpart U proceedings, but note that current § 423.2118 refers to a “CD” of the oral proceedings.

Current § 405.1042(b)(2) provides that if a party requests all or part of the record from an ALJ and an opportunity

to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90 calendar day adjudication period. We proposed to revise § 405.1042(b)(2) to state, if a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response. This proposed revision would clarify that a party may request a "copy of" all or part of the record, and would add that the request may be made to OMHA, or the ALJ or attorney adjudicator, because a party may request a copy of the record before it is assigned to an ALJ or attorney adjudicator. In addition, proposed § 405.1042(b)(2) would revise the discussion of the effect of requesting an opportunity to comment on the record on an adjudication period to remove the specific reference to a 90 calendar day adjudication period, because in accordance with proposed § 405.1016, an adjudication period may be 90 or 180 calendar days, or alternatively may be waived by the appellant and therefore not apply. We proposed at § 423.2042(b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042 does not address the circumstance in which a party requests a copy of the record but is not entitled to receive some of the documents in the record. For example, when an appeal involves multiple beneficiaries and one beneficiary requests a copy of the record, the records related to other beneficiaries may not be released to the requesting beneficiary unless he or she obtains consent from the other beneficiaries to release the records that pertain to them. Proposed § 405.1042(b)(3) would address the possibility that a party requesting a copy of the record is not entitled to receive the entire record. Specifically, we proposed in § 405.1042(b)(3) that if a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive (for example, personally identifiable information or protected health information), those portions of the record would not be furnished unless the requesting party obtains

consent from the individual. For example, if a beneficiary requests a copy of the record for an appeal involving multiple beneficiaries, the portions of the record pertaining to the other beneficiaries would not be furnished to the requesting beneficiary unless he or she obtains consent from the other beneficiaries. We stated in the proposed rule that we believed proposed § 405.1042(b)(3) would help ensure that parties are aware that they may not be entitled to receive all portions of the record. We proposed at § 423.2042(b)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received several comments requesting that parties be provided with a mechanism to request a copy of the administrative record after a notice of decision or dismissal is issued at the OMHA level but prior to requesting review of that determination by the Council. The commenters noted that parties may need to review the record after a decision or dismissal is issued to determine whether to pursue a subsequent appeal.

*Response:* After a case is adjudicated, OMHA releases custody of the administrative record and forwards it to a CMS contractor or SSA, at which time OMHA no longer has possession of the record to provide copies. If a request for review is filed with the Council, the regulations at §§ 405.1118 and 423.2118 address requesting and receiving a copy of the record from the Council. If a party wishes to request a copy of the record after a decision or dismissal is issued by an ALJ or attorney adjudicator and prior to filing a request for review with the Council, however, the requesting party may contact CMS or SSA to obtain a copy of the record.

*Comment:* We received one comment that expressed general support for the proposed changes, but requested that the agency clarify in the regulation that marking evidence as an exhibit does not create a legal presumption that the adjudicator actually considered it in rendering a decision. The commenter also requested that the agency reinforce that the good cause requirement for the submission of new evidence for the first time at the OMHA level does not apply to new evidence submitted by unrepresented beneficiaries and Medicaid state agencies.

*Response:* We thank the commenter for its support, but disagree that the regulation should incorporate the language suggested by the commenter, that marking evidence as an exhibit does not create a legal presumption that

the adjudicator considered it. The rules that we are finalizing require that evidence in the administrative record that the ALJ or the attorney adjudicator considers in making a decision is marked as an exhibit, and specifies certain evidence that is considered and therefore is marked as an exhibit. Because the rules already convey certain evidence will be considered, and in accordance with §§ 405.1046 and 423.2046, the notice of decision contains a summary of the clinical or scientific evidence used in making the determination, we believe what the ALJ or attorney adjudicator considered or did not consider will be evident from the record and decision. Further, adding the suggested language could cause confusion given that the rules prescribe that certain evidence will be considered and marked as evidence. In addition, if a party believes that certain evidence was marked as an exhibit but not appropriately considered by the ALJ or attorney adjudicator, or was not given appropriate weight in the decision or dismissal, the matter may be appealed to the Council and the Council will undertake a de novo review of the record. Under de novo review, the Council is not bound by the findings of the lower levels of adjudication and does not give deference to the determinations of the prior adjudicators. Given this standard of review and the clarification above, we do not believe that it is necessary or appropriate to specify in the regulations that marking an exhibit does not create a legal presumption that it was considered.

With respect to the commenter's second suggestion, as discussed in section II.B.3.i above, we are amending the language in § 405.1018(d) to clarify that the limitation on submitting new evidence for the first time at the OMHA level (as set forth in § 405.1018(c)) does not apply to evidence submitted by an unrepresented beneficiary, CMS or its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

*Comment:* One commenter requested clarification on the form that an individual's consent should take, and clarification on where the consent should be sent, under proposed §§ 405.1042(b)(3) and 423.2042(b)(3), regarding situations in which the party requesting a copy of the record is not entitled to receive some of the documents or information in the record because they pertain to another individual, and the requirement to obtain consent from the individual before OMHA will furnish a copy of the requested information.



*Response:* The proposed language does not specify a required form of individual consent; however, we recommend that parties use Form HHS-721 (Individual Appellant's Consent to Third-Party for Copies of the Individual Appellant's Record(s)), which is available on the HHS Web site at [www.hhs.gov](http://www.hhs.gov). Any individual consents obtained may be sent to OMHA, the assigned ALJ, or the assigned attorney adjudicator along with the party's request for a copy of the record consistent with §§ 405.1042(b) or 423.2042(b).

*Comment:* We received two comments suggesting that the proposed regulations did not sufficiently address the level of detail required in the index of the administrative record. One commenter noted that the lack of detail results in confusion about what evidence is actually before the adjudicator. The commenter recommended that seven days prior to a hearing OMHA should provide all parties with a detailed exhibit list identifying the following elements: The exhibit number, the exhibit range of pages, the subject of each exhibit, the author of each exhibit, the total number of pages in each exhibit, and the date(s) appearing on each exhibit. Another commenter stated that because the regulations provide no requirements on the level of detail to be used in the index of the administrative record, parties that want to request only a part of a record are unable to do so due to the general nature of the indexes.

*Response:* One of the proposed revisions to §§ 405.1042 and 423.2042 is to vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter. This change would allow OMHA to develop and implement agency-wide policies and uniform procedures for constructing the administrative record, including preparing and distributing the index of the administrative record, which we believe will help address both commenters' concerns.

We do not agree with the commenters that the regulations are the appropriate place for specific agency instructions on creating the index of the administrative record. OMHA is in the process of developing the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency. The OCPM describes OMHA case processing procedures in greater detail than generally is included in regulation and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA Web site

([www.hhs.gov/omha](http://www.hhs.gov/omha)), includes a detailed chapter on the administrative record and guidance on creating and distributing an index of the administrative record, which the OCPM currently refers to as exhibit lists. Current policy, as outlined in the OCPM, requires that a typed exhibit list be created. This standardized form is organized by categories of evidence and each exhibit number contains required minimum descriptions for some of the information recommended by the first commenter, including an exhibit number for each category, a description of the subject of each exhibit number, and the range of pages within each exhibit number. The OCPM does not require that the exhibit list contain a specific description of each document within a category or detailed information about individual exhibits within a category such as the dates of each exhibit or the author of each exhibit. It would be a significant burden on the staff assembling the record and creating the exhibit list to review each document and index information to the level of specificity suggested by the commenter. We believe that this administrative burden outweighs the limited potential benefits to the parties of having more specific information such as dates and authors of individual exhibits listed on an index. We also believe that by using standard categories for exhibits we are providing parties with useful information about the documents that will be considered by the adjudicator. For example, by placing all medical records in one exhibit category and providing a range of pages for that category, a party has information on the volume of records received to determine if it is likely that the record contains all of the necessary medical record evidence. While we understand that providing more specific descriptions, such as individual dates and authors for each exhibit, may further assist parties in confirming that certain evidence is in the record, we believe that there are other ways for parties to confirm that information, such as reviewing the total number of pages in each category, or by discussing the specific evidence at a hearing, or, if there are specific concerns regarding the evidence, by requesting a copy of all or any part of the record pursuant to §§ 405.1042(b) and 423.2042(b).

We are also not adopting the commenter's recommendation that OMHA send the exhibit list to all the parties seven days prior to the hearing. The OCPM already requires that an initial copy of the exhibit list be provided with the notice of hearing to

the parties and potential parties and participants who receive the notice, or at the first available opportunity before the hearing to the parties and potential parties and participants who responded to the notice of hearing. Under §§ 405.1022(a)(1) and 423.2022(a)(2), as finalized in this rule, the notice of hearing is mailed, transmitted, or served at least 20 calendar days before the hearing (except for expedited part D hearings, where notice is mailed, transmitted, or served at least 3 calendar days before the hearing), unless a party or participant agrees to fewer than 20 calendar days' or 3 calendar days' notice, as applicable. Therefore, the OCPM already requires that parties and potential parties and participants receive the exhibit list earlier than the commenter's recommendation of seven days prior to the hearing, or at the first available opportunity. (After the effective date of this final rule, we anticipate that revisions will be made to the OCPM to refer to an index of the administrative record, rather than an exhibit list.) In addition, proposed §§ 405.1042(b)(1) and 423.2042(b)(1) state that at any time while an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record, including a copy of the index of the administrative record. Finally, with regard to the second comment, we believe that if the exhibit lists are consistent across adjudicators, there will be improved clarity as to the types of documents within the specific exhibit categories. While it is not administratively possible given OMHA's docket and staffing constraints to create exhaustive lists of each document or item on an exhibit list, the implementation of uniform exhibiting procedures by OMHA, including the use of consistent exhibit categories, should make it easier for parties who only require certain documents or portions of a record to determine which exhibit number to request.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1042 and 423.2042 as proposed without modification.

u. Consolidated Proceedings (§§ 405.1044 and 423.2044)

Current §§ 405.1044 and 423.2044 explain that a consolidated hearing may be held at the request of an appellant or on the ALJ's own motion, if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ, and CMS is notified of an ALJ's

intention to conduct a consolidated hearing. If a consolidated hearing is conducted, current §§ 405.1044 and 423.2044 further provide that the ALJ may make a consolidated decision and record for the claims involved in the consolidated hearing, or may make a separate decision and record for each claim involved in the consolidated hearing. We stated in the proposed rule that this authority is useful in allowing an ALJ and the appellant to conduct a single proceeding on multiple appealed claims or other determinations that are before the ALJ, reducing time and expense for the appellant and the government to resolve the appealed matter. However, we stated that the current provisions have caused confusion, and have been limiting in circumstances in which no hearing is conducted, and proposed a number of revisions. 81 FR 43790, 43841–43842.

Current § 405.1044 uses the terms “requests for hearing,” “cases,” and “claims” interchangeably, and we stated in the proposed rule that this has resulted in confusion because an appeal, or “case,” before an ALJ may involve multiple requests for hearing if an appellant’s requests were combined into one appeal for administrative efficiency prior to being assigned to the ALJ. In addition, a request for hearing may involve one or more claims. We proposed in § 405.1044 to use the term “appeal” to specify that appeals may be consolidated for hearing, and a single decision and record may be made for consolidated appeals. We proposed to use “appeal” because an appeal is assigned a unique ALJ appeal number, for which a unique decision and record is made. We also proposed to move current § 405.1044(b) to new subsection (a)(2), and to also replace the term “combined” with “consolidated” for consistent use in terminology. Further, we proposed at § 423.2044 to adopt corresponding revisions to use consistent terminology in part 423, subpart U proceedings.

Current § 405.1044(a) through (d) describes when a consolidated hearing may be conducted, the effect on an adjudication period that applies to the appeal, and providing notice of the consolidated hearing to CMS. Proposed § 405.1044(a) would incorporate current § 405.1044(a) through (c) to combine the provisions related to a consolidated hearing. In addition, proposed § 405.1044(a)(4) would replace the current requirement to notify CMS that a consolidated hearing will be conducted in current § 405.1044(d) with a requirement to include notice of the consolidated hearing in the notice of hearing issued in accordance with

§§ 405.1020 and 405.1022. We stated that this would help ensure notice is provided to the parties and CMS, as well as its contractors, in a consistent manner, and reduce administrative burden on ALJs and their staff by combining that notice into the existing notice of hearing. We proposed at § 423.2044(a) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044(e) explains that when a consolidated hearing is conducted, the ALJ may consolidate the record and issue a consolidated decision, or the ALJ may maintain separate records and issue separate decisions on each claim. It also states that the ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable. However, there has been confusion on whether separate records may be maintained and a consolidated decision can be issued, as well as what must be included with the records when separate records are maintained. Proposed § 405.1044(b) would incorporate some of current § 405.1044(e) and add provisions for making a consolidated record and decision. We proposed at § 405.1044(b)(1) that if the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record, or a separate decision and record on each appeal. This proposed revision would maintain the current option to make a consolidated record and decision, or maintain separate records and issue separate decisions, but restructures the provision to highlight that these are two mutually exclusive options. This proposal is important because issuing a consolidated decision without also consolidating the record, or issuing separate decisions when a record has been consolidated, complicates effectuating a decision and further reviews of the appeal(s). We proposed in § 405.1044(b)(2) that, if a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing, are included in each individual administrative record. We stated that proposed § 405.1044(b)(2) would address the confusion that sometimes results in a copy of the audio recording of a consolidated hearing not being included in the administrative records

of each constituent appeal when separate records are maintained, by clarifying that if a separate decision and record is made, audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual record. We stated that this proposal is important because the record for each individual appeal must be complete. We proposed at § 423.2044(b)(1) and (b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044 does not contemplate a consolidated record and decision unless a consolidated hearing was conducted, which is limiting when multiple appeals for an appellant can be consolidated in a decision issued on the record without a hearing. We proposed to add § 405.1044(b)(3), which would provide that, if a hearing would not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ’s or attorney adjudicator’s own motion. We stated that this would provide authority for an ALJ or attorney adjudicator to make a consolidated decision and record on the same basis that a consolidated hearing may be conducted. We stated in the proposed rule that we believed this authority would add efficiency to the adjudication process when multiple appeals pending before the same adjudicator can be decided without conducting a hearing. We proposed at § 423.2044(b)(3) to adopt a corresponding provision for part 423, subpart U proceedings.

Current § 405.1044 also does not clearly address consolidating hearings for multiple appellants, including situations in which a beneficiary files a request for hearing on the same claim appealed by a provider or supplier, and the provider or supplier has other pending appeals that could be consolidated pursuant to current § 405.1044. We stated that the general practice is that a consolidated hearing is conducted for the appeals of a single appellant. This is supported by the reference to “an” appellant in current § 405.1044(b), and helps ensure the hearing and record is limited to protected information that the appellant is authorized to receive. Therefore, we proposed to add § 405.1044(c) to provide that consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the

amount in controversy requirement in accordance with § 405.1006, and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants. We stated that this would help ensure that beneficiary information is protected from disclosure to parties who are not authorized to receive it, including when a beneficiary requests a hearing for the same claim that has been appealed by a provider or supplier, and appeals of other beneficiaries' claims filed by the provider or supplier are also pending before the same ALJ or attorney adjudicator. We proposed at § 423.2044(c) to adopt a corresponding provision for part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received one comment asking whether a decision by OMHA's central docket to combine appeals prior to assignment to an ALJ can be challenged by the appellant if the appeals involve different disputed items, different bases for denial, and different issues, and, if so, what the process for that challenge is. The commenter had multiple questions about tracking the status and progress of individual appeals throughout the appeals process, the ability to separately appeal one or more of the individual claims, and rules regarding the administrative record in combined cases.

*Response:* Proposed § 405.1044 addresses the circumstances under which the proceedings for multiple ALJ appeals may be consolidated into one hearing, as well as the option for an ALJ or attorney adjudicator to make a consolidated decision and record, whether or not a hearing was conducted. Both of these actions would occur after assignment of the individual appeals to an ALJ or attorney adjudicator, either at the request of the appellant with the ALJ's or attorney adjudicator's approval or on the ALJ's or attorney adjudicator's own motion. However, we believe the commenter's question relates to the combination—not consolidation—of appealed reconsiderations under one ALJ appeal number prior to assignment to an ALJ or attorney adjudicator. OMHA internal case processing guidance permits the combination of appealed reconsiderations under a single ALJ appeal number prior to assignment for administrative efficiency when certain criteria are met. The commenter may review Chapter II–2 of the OCPM, which is available to the public on the OMHA

Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)), for more information on docketing and assignment of appeals, including combining appeals prior to assignment. Because the proposed changes to § 405.1044 relate to consolidation rather than combination of appeals prior to assignment, the commenters' specific questions regarding the combination of appeals are outside of the scope of the proposed rule.

*Comment:* We received two comments suggesting that the proposals go further and permit consolidation of all of an appellant's pending appeals at OMHA on the same issue, at the appellant's request, regardless of whether they are assigned to the same ALJ.

*Response:* We believe that proposed §§ 405.1044 and 423.2044, which we are finalizing in this rule, strike the appropriate balance between promoting administrative efficiency and maintaining rotational assignments, as well as allowing OMHA to balance workload among its ALJs and attorney adjudicators. Sections 405.1044 and 423.2044 contemplate that consolidation of proceedings is only available with respect to appeals pending before the same ALJ. We believe that allowing parties to request consolidation of proceedings that have been assigned to multiple adjudicators would be contrary to the concept of rotational assignment, disrupt the workflow of adjudicators, cause delays for other appellants, and add inefficiency to the process by requiring additional administrative resources to process such requests and reassign the appeals. However, as discussed previously, an appellant may request combination of multiple appealed reconsiderations on its request for hearing and, if the criteria for combination are met, OMHA accommodates such a request to the extent feasible by combining the appealed reconsiderations under a single ALJ appeal number. If OMHA is unable to accommodate the request and multiple appeals are established and assigned to a single adjudicator, the adjudicator can then consider consolidation of the appeals.

*Comment:* We received multiple comments that discussed the desire for uniform procedures for creating records in consolidated proceedings, conducting consolidated hearings, and creating audio recordings of consolidated appeals, as well as requested additional guidance for adjudicators on issuing consolidated decisions that contain separate factual findings, legal authorities, and legal analysis for each appeal at issue. One commenter urged the agency to provide additional

training and oversight on consolidated proceedings and requested that the agency make available a public resource regarding consolidated proceedings.

*Response:* The proposed revisions to §§ 405.1044 and 423.2044 were intended to reduce confusion and provide more consistent procedures for conducting consolidated hearings, and creating and maintaining records for consolidated appeals. OMHA is also in the process of developing the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency for adjudicating appeals under the rules. The OCPM describes OMHA case processing procedures in greater detail and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA Web site ([www.hhs.gov/omha](http://www.hhs.gov/omha)), includes detailed information on creating the administrative record both when an ALJ decides to make a consolidated decision and record, and when the ALJ decides to issue separate decisions and records. OMHA provides training to its ALJs, attorneys, and other staff to help ensure understanding and compliance with all regulations applicable to processing appeals, and will provide training on all aspects of this final rule.

*Comment:* One commenter expressed concern that the proposed language in § 405.1044(c) would complicate the consolidation of proceedings involving multiple appellants. The commenter noted that a provider's ability to consolidate proceedings will be hindered if it is unable to secure the necessary permissions from beneficiaries and asked for clarification on whether one of the HIPAA exceptions permitting providers to release protected health information in certain circumstances, even absent consent, may apply in this situation. Finally, the commenter recommended that the proposed regulation be revised to require only that a provider take "reasonable" steps to obtain such consent but that if consent cannot be obtained, that the parties will enter into a protective order to prohibit the unauthorized release of information and to require that the records be redacted as much as possible by removing, for example, the beneficiary's name, address, date of birth, and social security number. The commenter argued that by modifying § 405.1044(c) to allow for consolidation in proceedings involving multiple appellants subject to protective orders and redacted documentation, if necessary, the appeals process would be even more efficient while still ensuring beneficiary

information is as protected as possible in those circumstances.

*Response:* We believe the commenter is confusing an “appellant” with a “party” and we do not agree that § 405.1044(c) places unnecessary limits on the ability to consolidate proceedings for appeals filed by multiple appellants. An appellant is the party that files a request for hearing or request for review of a dismissal. For example, a provider that is a party may file a request for hearing for a service that it furnished to the beneficiary, who is also a party; in that instance, the provider is then also the appellant. In addition, if the provider files multiple requests for hearing for services that it furnished to different beneficiaries, the provider is the appellant in those appeals and proposed § 405.1044(c) would not apply because a single appellant is involved. However, proposed § 405.1044(c) would apply if multiple providers filed requests for hearing that were being consolidated because, in this case, there would be multiple appellants. In this situation, the providers may not have the necessary permissions from the beneficiaries to whom an individual provider did not furnish a service. We have a responsibility to protect individuals’ personally identifiable information and protected health information, and that responsibility takes priority over any potential gains in administrative efficiency. As we note in the summary above, the purpose of the consolidation rules is to reduce time and expense for appellants and the government. While the commenter suggests that there would be even greater administrative efficiencies gained if appeals from multiple appellants were also subject to consolidation without the limitations of § 405.1044(c), we believe that the limitations of § 405.1044(c) are necessary in order to protect personally identifiable information and protected health information. Moreover, we believe that the commenter’s alternative suggestions for safeguarding protected health information—entering protective orders and redacting certain information—would require additional administrative time and energy and, therefore, are contrary to the stated goal of administrative efficiency.

Although there may be rare and unusual circumstances where it may be permissible to release the protected health information of an individual to other parties (for example, a court order expressly authorizing such disclosure to litigants), we do not believe there are any generally applicable exceptions to the HIPAA privacy rules that would apply or be appropriate in this case to

permit the consolidation of proceedings involving multiple appellants where the appellants are unable to obtain authorization from the beneficiaries whose claims are at issue to disclose their protected information to the other parties and any participants. Consolidation of proceedings where multiple appellants are involved may result in disclosure of an individual’s protected health information to other individuals, including other involved beneficiaries, who do not have a right to receive the information and have no use for the information.

*Comment:* We received one comment in support of proposed § 405.1044(c) and the language that limits consolidated proceedings to appeals filed by the same appellant, unless multiple appellants have aggregated claims to meet the amount in controversy and the beneficiaries whose claims are at issue have authorized disclosure of protected information to other parties and any participants.

*Response:* We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1044 and 423.2044 as proposed without modification.

v. Notice of Decision and Effect of an ALJ’s or Attorney Adjudicator’s Decision (§§ 405.1046, 405.1048, 423.2046, and 423.2048)

Current §§ 405.1046 and 423.2046 describe the requirements for a decision and providing notice of the decision, the content of the notice, the limitation on a decision that addresses the amount of payment for an item or a service, the timing of the decision, and recommended decisions. Current §§ 405.1048 and 423.2048 describe the effects of an ALJ’s decision. However, the current sections only apply to a decision on a request for hearing, leaving ambiguities when issuing a decision on a request for review of a QIC or IRE dismissal. We proposed to consolidate the provisions of each section that apply to a decision on a request for hearing under proposed §§ 405.1046(a), 405.1048(a), 423.2046(a) and 423.2048(a), with further revisions discussed below, and introduce new §§ 405.1046(b), 405.1048(b), 423.2046(b) and 423.2048(b) to address a decision on a request for review of a QIC or IRE dismissal, as well as to revise the titles and provisions of the sections to expand their coverage to include decisions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We

also proposed to remove current § 405.1046(d), which addresses the timing of a decision on a request for hearing because it is redundant with § 405.1016 and could lead to confusion if a different adjudication period applies, such as a 180-calendar day period for an escalated request for QIC reconsideration, or if no adjudication period applies, such as when the period is waived by the appellant. Similarly, we proposed to remove current §§ 423.2046(a)(1) and (d) because the adjudication time frames discussed in the provisions are redundant with provisions in proposed § 423.2016. In addition, we proposed to re-designate current §§ 405.1046(e) and 423.2046(e), as proposed §§ 405.1046(c) and 423.2046(c) respectively, to reflect the revised structure of proposed §§ 405.1046 and 423.2046. 81 FR 43790, 43842–43843.

Current § 405.1046 states that an ALJ will issue a decision unless a request for hearing is dismissed. We proposed to revise § 405.1046(a) to state that an ALJ or attorney adjudicator would issue a decision unless the request for hearing is dismissed or remanded in order to accommodate those situations where the ALJ or attorney adjudicator remands a case to the QIC. We stated in the proposed rule that there has been confusion regarding the content requirements of the decision itself, as well as whether the findings or conclusions in a QIC reconsideration or the arguments of the parties may be referenced or adopted in the decision by reference. We stated that we believe that while the issues that are addressed in a decision are guided by the reconsideration, as well as the initial determination and redetermination, and a party may present arguments in a framework that reflects recommended findings and conclusions, the concept of a de novo review requires an ALJ or attorney adjudicator to make independent findings and conclusions. To address this confusion, we proposed in § 405.1046(a) to require that the decision include independent findings and conclusions to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others, though the ALJ or attorney adjudicator may ultimately make the same findings and conclusions. As discussed in and for the reasons stated in section III.A.3.t of the proposed rule and II.B.3.t of this final rule above, proposed § 405.1046(a)(2)(ii) would also require that if new evidence was submitted for the first time at the

OMHA level and subject to a good cause determination pursuant to proposed § 405.1028, the new evidence and good cause determination would be discussed in the decision. We proposed at § 423.2046(a) to adopt corresponding revisions for decisions on requests for hearing under part 423, subpart U, except the proposals related to discussing new evidence and good cause determinations related to new evidence because there are no current requirements to establish good cause for submitting new evidence in part 423, subpart U proceedings.

Current § 405.1046(a) requires that a decision be mailed. As OMHA transitions to a fully electronic case processing and adjudication environment, new options for transmitting a decision to the parties and CMS contractors may become available, such as through secure portals for parties or through inter-system transfers for CMS contractors. We proposed in § 405.1046(a) to revise the requirement that a decision be mailed to state that OMHA “-mails or otherwise transmits a copy of the decision,” to allow for additional options to transmit the decision as technologies develop. We proposed to revise § 423.2046(a) to adopt a corresponding revision for sending a decision under part 423, subpart U.

Current § 405.1046(a) also requires that a copy of the decision be sent to the QIC that issued the reconsideration. However, if the decision is issued pursuant to escalation of a request for a reconsideration, no reconsideration was issued. To address this circumstance, we proposed in § 405.1046(a) that the decision would be issued to the QIC that issued the reconsideration or from which the appeal was escalated. In addition, we proposed in § 405.1046(a) to replace “reconsideration determination” with “reconsideration” for consistency in referencing the QIC’s action. Current § 405.1046(a) also requires that a copy of the decision be sent to the contractor that made the initial determination. However, this requirement adds to the administrative burden on OMHA and we stated in the proposed rule we believed it was unnecessary in light of the requirement that a copy of the decision be sent to the QIC and the original decision is forwarded as part of the administrative record to another CMS contractor to effectuate the decision. Thus, we proposed in § 405.1046(a) to remove the requirement to send a copy of the decision to the contractor that issued the initial determination. In addition, we proposed in § 423.2046(a) to replace “reconsideration determination” with

“reconsideration” for consistency in referencing the IRE’s action in part 423, subpart U proceedings, but we did not propose to incorporate other changes proposed for § 405.1046(a) in proposed § 423.2046(a) because: (1) Escalation is not available in part 423, subpart U proceedings; and (2) the Part D plan sponsor, which makes the initial coverage determination, has an interest in receiving and reviewing ALJ and attorney adjudicator decisions related to an enrollee’s appeal of drug coverage.

As discussed above, we proposed to revise § 405.1046(b) to explain the process for making a decision on a request for review of a QIC dismissal. In accordance with proposed § 405.1004, we proposed in § 405.1046(b)(1) that unless the ALJ or attorney adjudicator dismisses the request for review of a QIC’s dismissal or the QIC’s dismissal is vacated and remanded, the ALJ or attorney adjudicator issues a written decision affirming the QIC’s dismissal. We proposed in § 405.1046(b)(1) that OMHA would mail or otherwise transmit a copy of the decision to all the parties that received a copy of the QIC’s dismissal because, as we stated in the proposed rule, we believe that the QIC would appropriately identify the parties who have an interest in the dismissal, and that notice of the decision on a request for review of a QIC dismissal to any additional parties is unnecessary. We also stated that we believe that notice to the QIC is not necessary when its dismissal is affirmed because it has no further obligation to take action on the request for reconsideration that it dismissed. We proposed in § 405.1046(b)(2)(i) that the decision affirming a QIC dismissal must describe the specific reasons for the determination, including a summary of the evidence considered and applicable authorities, but did not propose to require a summary of clinical or scientific evidence because such evidence is not used in making a decision on a request for a review of a QIC dismissal. In addition, we proposed that § 405.1046(b)(2)(ii) and (iii) would explain that the notice of decision would describe the procedures for obtaining additional information concerning the decision, and would provide notification that the decision is binding and not subject to further review unless the decision is reopened and revised by the ALJ or attorney adjudicator. We proposed to revise § 423.2046(b) to adopt corresponding provisions for a decision on requests for review of an IRE dismissal under part 423, subpart U, except that the notice of decision will only be sent to the

enrollee because only the enrollee is a party.

We proposed to revise the title of current § 405.1048 to read “The effect of an ALJ’s or attorney adjudicator’s decision” and to replace the current introductory statement in § 405.1048(a) that “The decision of the ALJ is binding on all parties to the hearing” with “The decision of the ALJ or attorney adjudicator is binding on all parties” to make the subsection applicable to decisions by attorney adjudicators and because the parties are parties to the decision regardless of whether a hearing was conducted. We also proposed in § 405.1048(b) that the decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in § 405.980. We proposed to revise § 423.2048 to adopt corresponding provisions for the effects of ALJ and attorney adjudicator decisions under part 423, subpart U.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter suggested that the contents of the notice of decision should include an explanation of why any evidence was excluded from the record, especially in the absence of any contradictory evidence. The commenter also suggested that OMHA should continue to send the notice of decision to the CMS contractor that made the initial determination because the decision provides feedback that can assist the contractor in making quality claim decisions.

*Response:* As discussed above and as provided for in proposed § 405.1046(a)(2)(ii), any new evidence submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed § 405.1028 will be discussed in the ALJ’s or attorney adjudicator’s decision. The decision will include a discussion of the good cause determination, regardless of whether good cause was found. We disagree that the presence or absence of contradictory evidence in the record would have any bearing on the ALJ’s or attorney adjudicator’s decision as to whether the party had good cause to submit evidence for the first time at the OMHA level. The absence of contradictory evidence would not explain why a party was unable to obtain and submit the evidence before the QIC issued its reconsideration, and would not fall under any of the other situations specified in § 405.1028(a)(2) for when an ALJ may find good cause

for the submission of evidence for the first time at the OMHA level.

With respect to sending a copy of the decision to the contractor that made the initial determination, as stated above and in the proposed rule, we believe that sending the ALJ's or attorney adjudicator's decision to a CMS contractor to effectuate the decision and a copy to the QIC will be sufficient to inform CMS and its contractors of the decision. We believe that in the majority of cases the benefit of sending an additional copy to the contractor that made the initial determination is outweighed by the administrative burden and costs, and CMS is in the best position to determine how decisions are shared among its contractors and whether or how those decisions should be used by its contractors.

*Comment:* Two commenters recommended explicitly prohibiting ALJs and attorney adjudicators from incorporating findings or conclusions offered by others in their decisions.

*Response:* We appreciate the commenters' support for our effort to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others. However, we do not believe it is necessary to rephrase this provision as a prohibition on incorporating the findings or conclusions of others. We believe that our proposal, to require that the decision include independent findings and conclusions, adequately expresses the requirement for de novo review, and are concerned that the language suggested by the commenter would unnecessarily preclude an ALJ or attorney adjudicator from including discussion of others' findings and conclusions in his or her decision for the purpose of discussing or analyzing them in the process of making his or her independent findings and conclusions. We believe the proposed language at § 405.1046(a), which we are finalizing in this rule, would preclude an ALJ or attorney adjudicator from merely adopting findings and conclusions offered by others, while providing the ALJ or attorney adjudicator with the flexibility to discuss or analyze the findings and conclusions offered by others, if appropriate in a specific appeal, in the process of making his or her independent findings and conclusions.

*Comment:* Two commenters urged HHS to ensure that beneficiaries always receive a written decision by regular mail, even when other methods of transmittal are available.

*Response:* The proposal to revise the current requirement in §§ 405.1046(a) and 423.2046(a)(3) that a decision be mailed, to require that OMHA "mails or otherwise transmits a copy of the decision," will help ensure that OMHA has the flexibility to work with appellants to take advantage of developing technologies. However, these added flexibilities will be based on appellants, including beneficiaries, opting into receiving notices and correspondences by means other than regular mail. For example, if a beneficiary affirmatively chooses to receive a decision via a secure internet portal instead of by mail, it would waste resources and be inefficient to require OMHA to also send a paper copy of the decision to the beneficiary by mail. The flexibility to work with developing technologies will allow OMHA to increase efficiency as we transition to a fully electronic case processing and adjudication environment, and provide all appellants with new options for receiving notices and other correspondence.

*Comment:* One commenter suggested adding a provision to §§ 405.1046(b)(2) and 423.2046(b)(2) explaining that appellants have the right to appeal a decision affirming a QIC or IRE dismissal to the Council, including instructions on how to initiate an appeal under this section and how to request a copy of the administrative record.

*Response:* We do not believe that it is appropriate to add a provision to §§ 405.1046(b)(2) and 423.2046(b)(2) explaining how to appeal a decision affirming a QIC or IRE dismissal to the Council because a decision affirming a QIC or IRE dismissal is not appealable to the Council. Incorporating provisions from current §§ 405.1004(c) and 423.2004(c) that make a decision on a QIC or IRE dismissal not subject to further review, proposed §§ 405.1046(b)(2)(iii) and 423.2046(b)(2)(iii) explain that a decision affirming a QIC or IRE dismissal is binding and not subject to further review, unless the decision is reopened and revised by the ALJ or attorney adjudicator. We explained in the preamble to the 2005 Interim Final Rule implementing current § 405.1004(c) that limiting review of dismissals to one level of appeal balances the need for review with the need for finality. 70 FR 11420, 11444. Because dismissals are based on procedural circumstances involved with the appeal request rather than the merits of whether the claim is payable, we determined that further review was not necessary, and we did not propose any

changes to the limitation on review of dismissals in this final rule.

With respect to the commenter's suggestion to include instructions on how to obtain a copy of the administrative record in a notice of decision, we note that §§ 405.1046(a)(2)(iii), (b)(2)(ii), 423.2046(a)(2)(ii), and (b)(2)(ii), as finalized, require that a notice of decision must include the procedures for obtaining additional information concerning the decision, which would include information on how to obtain a copy of the administrative record. As discussed in section II.B.3.t of this final rule above, after a case is adjudicated, OMHA releases custody of the administrative record and forwards it to a CMS contractor or SSA. We will explore the possibility of adding contact information for the CMS contractor or SSA to the notice of decision; however, we believe that this would best be managed through internal policy at OMHA and not as part of this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1046, 405.1048, 423.2046, and 423.2048 as proposed without modification.

w. Removal of a Hearing Request From an ALJ to the Council (§§ 405.1050 and 423.2050)

Current §§ 405.1050 and 423.2050 explain the process for the Council to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. We proposed to replace "an ALJ" with "OMHA" in the section title, and to replace "pending before an ALJ" with "pending before OMHA," and "the ALJ send" with "OMHA send" in the section text. In accordance with section II.B of the proposed rule and II.A.2 of this final rule above, these proposed revisions would provide that a request for hearing may be removed to the Council regardless of whether the request is pending before an ALJ or an attorney adjudicator. We did not propose to replace the last instance of "ALJ" in the section text because it refers specifically to hearings conducted by an ALJ. 81 FR 43790, 43843.

We received no comments on these proposals, other than: (1) Comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or

appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1050 and 423.2050 as proposed without modification.

x. Dismissal of a Request for Hearing or Request for Review and Effect of a Dismissal of a Request for Hearing or Request for Review (§§ 405.1052, 405.1054, 423.2052 and 423.2054)

Current §§ 405.1052 and 423.2052 describe the circumstances in which a request for hearing may be dismissed and the requirements for a notice of dismissal, and current §§ 405.1054 and 423.2054 describe the effect of a dismissal of a request for hearing. However, both current sections apply to a dismissal of a request for hearing, leaving ambiguities when issuing a dismissal of a request for review of a QIC or IRE dismissal. We proposed to maintain the provisions of each section that apply to a dismissal of a request for hearing in proposed §§ 405.1052(a), 405.1054(a), 423.2052(a) and 423.2054(a), with further revisions discussed below. 81 FR 43790, 43843–43845. We proposed to introduce new §§ 405.1052(b), 405.1054(b), 423.2052(b) and 423.2054(b) to address a dismissal of a request for review of a QIC or IRE dismissal. However, we proposed to re-designate and revise §§ 405.1052(a)(1) and 423.2052(a)(1), as discussed below, and re-designate the remaining paragraphs in §§ 405.1052(a) and 423.2052(a) accordingly. We also proposed to remove the introductory language to current §§ 405.1052 and 423.2052 because it is unnecessary to state that a dismissal of a request for hearing is in accordance with the provisions of the section, as the provisions are themselves binding authority and state in full when a request for hearing may be dismissed. In addition, we proposed to revise the titles of the sections to expand their coverage to include dismissals of requests to review a QIC or IRE dismissal. Furthermore, we proposed to re-designate and revise current §§ 405.1052(b) and 423.2052(b), which describe notices of dismissal, as proposed §§ 405.1052(d) and 423.2052(d) respectively, to reflect the

revised structure of proposed §§ 405.1052 and 423.2052. We also proposed to remove current § 423.2052(a)(8) and (c) because current § 423.2052(a)(8) restates current § 423.1972(c)(1), which already provides that a request for hearing will be dismissed if the request itself shows that the amount in controversy is not met, and current § 423.2052(c) restates current § 423.1972(c)(2), which already provides that if after a hearing is initiated, the ALJ finds that the amount in controversy is not met, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal. We noted that a dismissal would be warranted in these circumstances pursuant to current § 423.2052(a)(3), which is carried over as proposed § 423.2052(a)(2) because the enrollee does not have a right to a hearing if the amount in controversy is not met.

We proposed to re-designate and revise current §§ 405.1052(a)(1) and 423.2052(a)(1) as proposed §§ 405.1052(c) and 423.2052(c) to separately address dismissals based on a party's withdrawal. We proposed in §§ 405.1052(c) and 423.2052(c) to include withdrawals of requests to review a QIC dismissal because we also proposed to add provisions to address other dismissals of those requests at §§ 405.1052(b) and 423.2052(b). We also proposed that an ALJ or attorney adjudicator may dismiss a request for review of a QIC dismissal based on a party's withdrawal of his or her request because as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), both ALJs and attorney adjudicators would be able to adjudicate requests to review a QIC dismissal. In addition, we proposed that an ALJ or attorney adjudicator may dismiss a request for hearing based on a party's withdrawal of his or her request. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we believe that well-trained attorneys can efficiently perform a review of these requests and issue dismissals. We stated in the proposed rule that we believe using attorney adjudicators to the maximum extent possible would help OMHA be more responsive to appellants and allow ALJs to focus on conducting hearings and issuing decisions. We also proposed to revise the language in current §§ 405.1052(a)(1) and 423.2052(a)(1) (as re-designated in proposed §§ 405.1052(c) and 423.2052(c)) to (1) replace "notice of the hearing decision" with "notice of the decision, dismissal or remand" to reflect that a decision

may be issued without a hearing, and to reflect other possible outcomes of the proceeding (dismissal and remand), and (2) clarify that a request to withdraw a request for hearing may be made orally at a hearing before the ALJ because only an ALJ may conduct a hearing.

Current § 405.1052(a)(2) describes three possible alternatives for dismissing a request for hearing when the party that requested the hearing, or the party's representative, does not appear at the time and place set for the hearing. We stated in the proposed rule that the current alternatives have caused confusion for appellants in understanding whether they are required to submit a statement explaining a failure to appear. Further, current provisions do not require evidence in the record to document an appellant was aware of the time and place of the hearing, and we stated that this has resulted in remands from the Council. We proposed to simplify the provision to provide two alternatives, and to require that contact has been made with an appellant and documented, or an opportunity to provide an explanation for failing to appear has been provided before a request for hearing is dismissed for failing to appear at the hearing. We proposed at § 405.1052(a)(1)(i) to set forth the first alternative which would provide that a request for hearing may be dismissed if the party that filed the request was notified before the time set for hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing or does contact the ALJ but does not provide good cause for not appearing. We proposed at § 405.1052(a)(1)(ii) to set forth the second alternative which would provide that a request for hearing may be dismissed if the record does not contain documentation that the party acknowledged the notice of hearing, but the ALJ sends a notice to the party at his or her last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does respond but does not provide good cause for not appearing. In either circumstance, we proposed to maintain in § 405.1052(a)(1) the current standard that in determining whether good cause exists, the ALJ considers any physical, mental, educational, or linguistic limitations that the party may have identified. We stated in the proposed rule that we believed



proposed § 405.1052(a)(1) would help ensure that appellants have consistent notice of a possible dismissal for failure to appear and an opportunity to provide a statement explaining why they did not appear before a dismissal is issued. We proposed to revise § 423.2052(a)(1) to adopt corresponding revisions for dismissing a request for hearing under part 423, subpart U.

Current OMHA policy provides that a request for hearing that does not meet the requirements of current § 405.1014 may be dismissed by an ALJ after an opportunity is provided to the appellant to cure an identified defect (OCPM, division 2, chapter 3, section II-3-6 D and E). We stated that a dismissal is appropriate because as an administrative matter, the proceedings on the request do not begin until the information necessary to adjudicate the request is provided and the appellant sends a copy of the request to the other parties. Additionally, a request cannot remain pending indefinitely once an appellant has demonstrated that he or she is unwilling to provide the necessary information or to send a copy of the request to the other parties.

Therefore, we proposed at § 405.1052(a)(7) to explain that a request for hearing may be dismissed if the request is not complete in accordance with proposed § 405.1014(a)(1) or the appellant did not send copies of its request to the other parties in accordance with proposed § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send copies of the request to the other parties. We stated in the proposed rule that we believed adding this provision would emphasize the importance of following the requirements for filing a request for hearing, and clarify the outcome if the requirements are not met and the appellant does not cure identified defects after being provided with an opportunity to do so. We proposed at § 423.2052(a)(7) to adopt a corresponding provision for dismissing a request for hearing under part 423, subpart U.

As discussed above, we proposed to add § 405.1052(b) to explain when a request for review of a QIC dismissal would be dismissed. Under proposed § 405.1052(b), a request for review could be dismissed in the following circumstances: (1) The person or entity requesting the review has no right to the review of the QIC dismissal under proposed § 405.1004; (2) the party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline; (3) a

beneficiary or beneficiary's representative filed the request for review and the beneficiary passed away while the request for review is pending and all of the following criteria apply: (i) a surviving spouse or estate has no remaining financial interest in the case, (ii) no other individuals or entities have a financial interest in the case and wish to pursue an appeal, and (iii) no other individual or entity filed a valid and timely request for a review of the QIC dismissal; and (4) the appellant's request for review is not complete in accordance with proposed § 405.1014(a)(1) or the appellant does not send a copy of the request to the other parties in accordance with proposed § 405.1014(d), after being provided with an opportunity to complete the request and/or send a copy of the request to the other parties. We stated in the proposed rule that we believed these provisions would encompass the reasons for dismissing a request for a review of a QIC dismissal, and are necessarily differentiated from dismissing a request for hearing because, as explained in section III.A.3.c of the proposed rule and II.B.3.c of this final rule above, we also stated that we did not believe there is a right to a hearing for requests for a review of a QIC dismissal. We proposed at § 423.2052(b) to adopt corresponding provisions for dismissing requests for a review of an IRE dismissal under part 423, subpart U proceedings.

As discussed above, current § 405.1052(b) describes the requirements for providing notice of the dismissal and we proposed to re-designate the paragraph as proposed § 405.1052(d). For the same reasons discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule above for allowing a notice of a decision to be provided by means other than mail, we proposed in § 405.1052(d) that OMHA may mail or "otherwise transmit" notice of a dismissal. We proposed to revise § 423.2052(d) to adopt a corresponding revision for notices of dismissal under part 423, subpart U.

Current § 405.1052(b) requires notice of the dismissal to be sent to all parties at their last known address. However, we stated in the proposed rule that we believed that requirement is overly inclusive and causes confusion by requiring notice of a dismissal to be sent to parties who have not received a copy of the request for hearing or request for review that is being dismissed. Thus, we proposed to revise § 405.1052(d) to state that the notice of dismissal is sent to the parties who received a copy of the request for hearing or request for review

because only those parties are on notice that a request was pending. In addition, we proposed at § 405.1052(d) that if a party's request for hearing or request for review is dismissed, the appeal would proceed with respect to any other parties who also filed a valid request for hearing or review regarding the same claim or disputed matter. This would address the rare circumstance in which more than one party submits a request, but the request of one party is dismissed. In that circumstance, the appeal proceeds on the request that was not dismissed, and the party whose request was dismissed remains a party to the proceedings but does not have any rights associated with a party that filed a request, such as the right to escalate a request for hearing. We did not propose a corresponding revision to § 423.2052(c) because only the enrollee is a party to an appeal under part 423, subpart U.

Current § 405.1052 does not include authority for an ALJ to vacate his or her own dismissal, and instead requires an appellant to request the Council review an ALJ's dismissal. As explained in the 2005 Interim Final Rule (70 FR 11465), the authority for an ALJ to vacate his or her own dismissal was not regarded as an effective remedy because the record was no longer in the ALJ hearing office, and the resolution was complicated when appellants simultaneously asked the ALJ to vacate the dismissal order and asked the Council to review the dismissal. However, we stated that in practice, the lack of the authority for an ALJ to vacate his or her own dismissal has constrained ALJs' ability to correct erroneous dismissals that can be easily remedied by the ALJ, and has caused unnecessary work for the Council. We proposed to add § 405.1052(e) to provide the authority for an ALJ or an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), to vacate his or her own dismissal within 6 months of the date of the notice of dismissal, in the same manner as a QIC can vacate its own dismissal. We stated in the proposed rule that we believed that this authority would reduce unnecessary appeals to the Council and provide a more timely resolution of dismissals for appellants, whether the dismissal was issued by an ALJ or attorney adjudicator. We also noted that the coordination for obtaining the administrative record and addressing instances in which an appellant also requests a review of the dismissal by the Council can be addressed through operational coordination among CMS, OMHA, and the DAB. We proposed in

§ 423.2052(e) to adopt a corresponding provision for vacating a dismissal under part 423, subpart U.

To align the effects of a dismissal with proposed § 405.1052(e), we proposed to add § 405.1054(a) to state that the dismissal of a request for hearing is binding unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e), in addition to the current provision that allows the dismissal to be vacated by the Council under § 405.1108(b). To explain the effect of a dismissal of a request for review of a QIC dismissal, consistent with § 405.1004, we proposed in § 405.1054(b) to provide that the dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e). We proposed in § 423.2054 to adopt corresponding revisions for the effect of dismissals of request for hearing and requests for review of an IRE dismissal under part 423, subpart U.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on this proposal. The commenter suggested that additional leeway should be allowed for unrepresented beneficiaries to complete a request for hearing and/or send copies of the request to the other parties before the request is dismissed, and dismissals for failing to meet these requirements should be used sparingly. The commenter also stated that the notice of dismissal should always be provided to beneficiaries by regular mail in addition to any other method of transmission that is used.

*Response:* As discussed above and in the proposed rule, we believe that the provision allowing for dismissal of an incomplete request for hearing or review of a QIC or IRE dismissal is necessary to emphasize the importance of the information required for filing a complete request, and to clarify the outcome if the required information is not provided after an opportunity to complete the request is provided. This provision will bring efficiencies to the appeals process by helping to ensure that appellants furnish all information necessary to adjudicate the request to the adjudicator and the other parties as early in the process as possible and preventing appeals from remaining pending indefinitely if an appellant has demonstrated an unwillingness to complete the request. If there is information missing in a beneficiary's request for hearing or review of a QIC

or IRE dismissal, the beneficiary will receive a letter explaining what information is missing, and providing the address and phone number of the OMHA field office to contact with any questions. In addition, OMHA maintains a dedicated beneficiary help line to assist beneficiaries with questions they may have about the appeals process at OMHA, including helping them to understand what information is necessary to complete the request.

However, as discussed in section II.B.3.g.v of this final rule above, we agree that unrepresented beneficiaries may have difficulty meeting the copy requirement of proposed § 405.1014(d), and should be exempt from the consequence of failing to provide a copy of a request for hearing or review of a dismissal to the other parties. Consequently, we are revising § 405.1052(a)(7) and (b)(4) to provide that a request filed by an unrepresented beneficiary will not be dismissed if the appellant fails to send a copy of the request to the other parties in accordance with proposed § 405.1014(d).

With respect to the commenter's suggestion to always provide beneficiaries with the notice of dismissal by regular mail, we refer the commenter to our response to a similar comment in section II.B.3.v of this final rule above, where we explain why we do not believe a notice of decision sent to a beneficiary under § 405.1046(a) and § 423.2046(a) should always be sent by mail in addition to any other method of transmission that is used. We believe this explanation responds to the commenter's same suggestion with regard to a notice of dismissal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1052, 405.1054, 423.2052 and 423.2054 as proposed, with the following modification. We are amending § 405.1052(a)(7) and (b)(4) to state that a request filed by an unrepresented beneficiary will not be subject to dismissal if the appellant fails to send a copy of the request to the other parties in accordance with § 405.1014(d).

#### 4. Applicability of Medicare Coverage Policies (§§ 405.1060, 405.1062, 405.1063, 423.2062, and 423.2063)

Current § 405.1060 addresses the applicability of national coverage determinations (NCDs) to claim appeals brought under part 405, subpart I and provides that an ALJ and the Council may not disregard, set aside, or

otherwise review an NCD, but may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim. Current § 405.1062 addresses the applicability of local coverage determinations (LCDs) and other policies, and specifies that ALJs and the Council are not bound by LCDs, local medical review policies (LMRPs), or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Similarly, current § 423.2062 states that ALJs and the Council are not bound by CMS program guidance but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Current §§ 405.1062 and 423.2062 also provide that an ALJ or Council decision to disregard a policy applies only to the specific claim being considered and does not have precedential effect. Further, § 405.1062 states that an ALJ or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. Current §§ 405.1063 and 423.2063 address the applicability of laws, regulations, and CMS Rulings, and provide that all laws and regulations pertaining to the Medicare program (and for § 405.1063 the Medicaid program as well), including but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs and the Council, and consistent with § 401.108, CMS Rulings are binding on all HHS components that adjudicate matters under the jurisdiction of CMS.

We proposed to revise §§ 405.1060, 405.1062, 405.1063, 423.2062, and 405.2063 to replace "ALJ" or "ALJs" with "ALJ or attorney adjudicator" or "ALJs or attorney adjudicators" except in the second sentence of § 405.1062(c). 81 FR 43790, 43846. We stated that an attorney adjudicator would issue certain decisions and dismissals and therefore would apply the authorities addressed by these sections. We stated in the proposed rule that requiring the attorney adjudicators to apply the authorities in the same manner as an ALJ would provide consistency in the adjudication process, regardless of who

is assigned to adjudicate a request for an ALJ hearing or request for review of a QIC or IRE dismissal. We did not propose to revise the second sentence in current § 405.1062(c) because attorney adjudicators would not review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 (part 426 appeals are currently heard by ALJs in the Civil Remedies Division of the DAB).

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1060, 405.1062, 405.1063, 423.2062, and 423.2063 as proposed without modification.

#### 5. Council Review and Judicial Review

##### a. Council Review: General (§§ 405.1100, 423.1974 and 423.2100)

As described below, we proposed a number of changes to §§ 405.1100, 423.1974 and 423.2100 with respect to Council review, generally. 81 FR 43790, 43846–43847. Current § 405.1100 discusses the Council review process. Current § 405.1100(a) states that the appellant or any other party to the hearing may request that the Council review an ALJ's decision or dismissal. We proposed to revise § 405.1100(a) to replace “the hearing” with “an ALJ's or attorney adjudicator's decision or dismissal,” and “an ALJ's decision or dismissal,” with “the ALJ's or attorney adjudicator's decision or dismissal” because the parties are parties to the proceedings and the resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), an attorney adjudicator would be able to issue certain decisions or dismissals for which Council review may be requested.

Current § 423.1974 states that an enrollee who is dissatisfied with an ALJ hearing decision may request that the Council review the ALJ's decision or dismissal as provided in § 423.2102, and current § 423.2100(a) states that consistent with § 423.1974, the enrollee may request that the Council review an ALJ's decision or dismissal. We

proposed to revise § 423.1974 to replace “ALJ hearing decision” with “an ALJ's or attorney adjudicator's decision or dismissal,” and to revise §§ 423.1974 and 423.2100(a) to replace “ALJ's decision or dismissal” with “an ALJ's or attorney adjudicator's decision or dismissal” because the parties are parties to the proceedings and resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), an attorney adjudicator may issue a decision or dismissal for which Council review may be requested.

Current § 405.1100(b) provides that under the circumstances set forth in §§ 405.1104 and 405.1108, an appellant may request escalation of a case to the Council for a decision even if the ALJ has not issued a decision or dismissal in his or her case. We proposed to revise § 405.1100(b) to provide that under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

We stated in the proposed rule that these revisions would reference § 405.1016, which, as discussed in section III.A.3.h of the proposed rule and II.B.3.h of this final rule above, would replace the current § 405.1104 provisions for escalating a case from the OMHA level to the Council. We stated that they would also provide that in addition to potentially issuing a decision or dismissal, an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), may issue a remand—this would present a complete list of the actions that an ALJ or attorney adjudicator could take on an appeal.

Current §§ 405.1100(c) and 423.2100(b) and (c) state in part that when the Council reviews an ALJ's decision, it undertakes a de novo review, and the Council issues a final decision or dismissal order or remands a case to the ALJ. We proposed to revise §§ 405.1100(c) and 423.2100(b) and (c) to state that when the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a de novo review and may remand a case to an ALJ or attorney adjudicator, so that the same standard for review is applied to ALJ and attorney adjudicator decisions. We also proposed to revise §§ 405.1100(c) and 423.2100(c) to state that the Council may remand an attorney adjudicator's decision to the attorney adjudicator so that like an ALJ, the attorney adjudicator can take the appropriate action ordered by the Council (however,

if the Council were to order that a hearing must be conducted, the case would be transferred to an ALJ upon remand to the attorney adjudicator because only an ALJ may conduct a hearing).

Current § 423.2100(c) and (d) provide that the Council issues a final decision, dismissal order, or remand no later than the period of time specified in the respective paragraph, beginning on the date that the request for review is received by the entity specified in the ALJ's written notice of decision. We proposed to revise § 423.2100(c) and (d) to state that the period of time begins on the date that the request for review is received by the entity specified in the ALJ's or attorney adjudicator's written notice of decision because an attorney adjudicator may also issue a decision, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to revise § 423.2100(c) to correct a typographical error by inserting “day” into the current “90 calendar period,” so it is clear to enrollees that the period of time being referenced is the 90 calendar day period.

Current § 405.1100(d) states in part that when deciding an appeal that was escalated from the ALJ level to the Council, the Council will issue a final decision or dismissal order or remand order within 180 calendar days of receipt of the appellant's request for escalation. A remand from the Council after an appeal is escalated to it is exceedingly rare and done in circumstances in which the Council must remand to an ALJ so that the ALJ may obtain information under current § 405.1034 that is missing from the written record and essential to resolving the issues on appeal, and that information can only be provided by CMS or its contractors, because the Council does not have independent authority to obtain the information from CMS or its contractors. In addition, an appeal may have not yet have been assigned to an ALJ, or could be assigned to an attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), when the appeal was escalated by the appellant. We proposed to revise § 405.1100(d) to state that if the Council remands an escalated appeal, the remand is to the OMHA Chief ALJ because the rare and unique circumstances in which an escalated appeal is remanded by the Council require immediate attention that the OMHA Chief ALJ is positioned to provide to minimize delay for the appellant, and to minimize confusion if the case was not assigned to an ALJ or

attorney adjudicator when it was escalated.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received one comment that supported the proposal that the Council remand escalated appeals to the Chief ALJ to minimize confusion and delay for appellants. The commenter also requested that language be added to the regulation requiring the Council to acknowledge receipt of an appellant's request for review due to the Council's considerable backlog and delay in issuing decisions.

*Response:* We thank the commenter for its support and agree that the Council should acknowledge receipt of an appellant's request for review. Since 2009, it has been and will continue to be, the practice of the Council to issue acknowledgment letters to appellants when a request for review is received and docketed. In addition, the Council has started accepting electronically filed requests for review, using the Medicare Operations Divisions Electronic Filing (MOD E-File) system, located at <https://dab.E-File.hhs.gov/mod>. An appellant that electronically files a request for review will receive an automated email response that acknowledges receipt of the request for review as well as provides the docket number assigned to the case. Finally, appellants may also use MOD E-File to check the status of appeals, regardless of whether the request for review was electronically filed. Appellants can check the status of an appeal by the docket number stated in the acknowledgment letter or email or by the ALJ appeal number. Because of the Council's continued commitment to issuing acknowledgments, as well as electronic enhancements that allow parties to check the status of appeals pending before the Council, we find it unnecessary to modify the proposed regulation.

*Comment:* One commenter questioned the current rule granting the Council, which is comprised of Administrative Appeals Judges (AAJs), the authority to conduct de novo reviews of ALJ decisions. The commenter was concerned that AAJs lack the independence of ALJs and are beholden to the agency for their positions and, therefore, AAJs are not best suited to review ALJ decisions. Accordingly, the commenter suggested various revisions to the current rule to address this concern that are unrelated to the proposed rule.

*Response:* We appreciate the commenter's opinion and suggestion, but its comment is beyond the scope of

the proposed rule, and thus we are not addressing it in this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1100, 423.1974 and 423.2100 as proposed without modification.

b. Request for Council Review When ALJ Issues Decision or Dismissal (§§ 405.1102 and 423.2102)

As described below, we proposed a number of changes to §§ 405.1102 and 423.2102, which discuss requests for Council review when an ALJ issues a decision or dismissal. 81 FR 43790, 43847. Current §§ 405.1102(a)(1) and 423.2102(a)(1) provide that a party or enrollee, respectively, to "the ALJ hearing" may request a Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's decision or dismissal, which is in accordance with the criteria specified in current §§ 405.1102 and 423.2102. However, we stated in the proposed rule that a party or enrollee is a party to the proceedings and resulting decision or dismissal, and may appeal the decision or dismissal regardless of whether a hearing was conducted in the appeal, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney adjudicator may issue a decision or dismissal for which Council review may be requested. To help ensure there is no confusion that a party or enrollee may seek Council review even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal, we proposed to revise §§ 405.1102(a)(1) and 423.2102(a)(1) to state a party or enrollee to a decision or dismissal issued by an ALJ or attorney adjudicator may request Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

Current §§ 405.1102(c) and 423.2102(c) provide that a party or enrollee, respectively, does not have a right to seek Council review of an ALJ's remand to a QIC or IRE, or an ALJ's affirmation of a QIC's or IRE's dismissal of a request for reconsideration. However, under current §§ 405.1004(c) and 423.2004(c), a party or enrollee, respectively, may currently seek Council review of a dismissal of a request for review of a QIC or IRE dismissal because, as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule above, an ALJ does not currently have the

authority to vacate his or her own dismissal. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney adjudicator could adjudicate requests for a review of a QIC or IRE dismissal. In addition, proposed §§ 405.1052(e) and 423.2052(e) would establish the authority for an ALJ or attorney adjudicator to vacate his or her own dismissal, and in accordance with the policy that a review of a dismissal is only reviewable at the next level of appeal, as discussed in section III.A.3.c of the proposed rule and II.B.3.c of this final rule above, proposed §§ 405.1102(c) and 423.2102(c) would be revised to indicate that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's dismissal of a request for review of a QIC dismissal. Therefore, we proposed at §§ 405.1102(c) and 423.2102(c) to add that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC or IRE, affirmation of a QIC's or IRE's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC or IRE dismissal.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment supporting the revised language that Council review may be sought even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal.

*Response:* We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1102 and 423.2102 as proposed without modification.

c. Where a Request for Review or Escalation May Be Filed (§§ 405.1106 and 423.2106)

As discussed below, we proposed a number of changes to §§ 405.1106 and 423.2106 with respect to where a request for review or escalation may be filed. 81 FR 43790, 43847–43848. Current §§ 405.1106(a) and 423.2106 provide that when a request for a Council review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action, and under § 405.1106, the appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision or notice of dismissal. The sections also

explain that if the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action, and upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame. In addition, current § 405.1106(b) discusses that if an appellant files a request to escalate an appeal to the Council because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the Council, and the appellant must also send a copy of the request for escalation to the other parties and failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for Council review.

We proposed in §§ 405.1106 and 423.2106 to replace all instances of "ALJ" with "ALJ or attorney adjudicator," and "ALJ's action" with "ALJ's or attorney adjudicator's action," to provide that the sections apply to decisions and dismissals issued by an attorney adjudicator as well, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore appellants would have the same right to seek Council review of the attorney adjudicator's decision or dismissal, and the Council would have the authority to take the same actions in reviewing an attorney adjudicator's decision or dismissal. We also proposed to replace "a copy of the hearing decision under § 405.1046(a) or a copy of the notice of dismissal under § 405.1052(b)" in § 405.1106(a) with "notice of the decision or dismissal," because §§ 405.1046 and 405.1052 provide for notice of a decision or dismissal, respectively, to be sent, and a decision or dismissal may be issued by an ALJ or attorney adjudicator without conducting a hearing. In addition, in describing the consequences of failing to send a copy of the request for review to the other parties, we proposed to replace "until all parties to the hearing" in § 405.1106(a) to "until all parties to the ALJ or attorney adjudicator decision or dismissal," to align the language with the preceding sentences.

We proposed to revise § 405.1106(b) to align the paragraph with the revised escalation process proposed at

§ 405.1016 (see section III.A.3.h.i of the proposed rule and II.B.3.h.i of this final rule above). Specifically, we proposed to revise § 405.1106(b) to state that if an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. This proposed revision would align this section with the revised process in proposed § 405.1016 by specifying that the request for escalation is filed with OMHA and removing the requirement for an appellant to also file the request with the Council. In addition, proposed § 405.1106(b) would specify that the request for escalation must be sent to the other parties who were sent a copy of the QIC reconsideration, which would align with the parties to whom the appellant is required to send a copy of its request for hearing. Proposed § 405.1106(b) would also refer to "an applicable adjudication period" under § 405.1016, to align the terminology and because an adjudication period may not apply to a specific case (for example, if the appellant waived an applicable adjudication time frame). Finally, proposed § 405.1106(b) would provide that failing to copy the other parties would toll the Council's adjudication deadline until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation, rather than notice of the request for Council review as is currently required, because the revised escalation process proposed at § 405.1016 would remove the requirement to file a request for Council review when escalation is requested from the OMHA to the Council level.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1106 and 423.2106 as proposed without modification.

d. Council Actions When Request for Review or Escalation Is Filed (§§ 405.1108 and 423.2108)

As described below, we proposed a number of changes to §§ 405.1108 and 423.2108, which describe the actions the Council may take upon receipt of a request for review or, for § 405.1108, a request for escalation. 81 FR 43790, 43848. We proposed at § 405.1108(d) introductory text to replace "ALJ level" with "OMHA level" to provide that the Council's actions with respect to a request for escalation are the same regardless of whether the case was pending before an ALJ or attorney adjudicator, or unassigned at the time of escalation. We also proposed at § 405.1108(d)(3) to replace "remand to an ALJ for further proceedings, including a hearing" with "remand to OMHA for further proceedings, including a hearing" because we stated in the proposed rule that we believed the Council could remand an escalated case to an ALJ or attorney adjudicator for further proceedings, but if the Council ordered that a hearing be conducted, the case would need to be remanded to an ALJ. We did not propose any corresponding changes to § 423.2108 because escalation is not available for Part D coverage appeals.

We also proposed in §§ 405.1108(b) and 423.2108(b), to provide that the dismissal for which Council review may be requested is a dismissal of a request for a hearing, because as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule above, proposed §§ 405.1054(b) and 423.2054(b) would provide that a dismissal of a request for a review of a QIC or IRE dismissal of a request for reconsideration is binding and not subject to further review. Finally, we proposed to replace all remaining references in §§ 405.1108 and 423.2108 to "ALJ" with "ALJ or attorney adjudicator" and "ALJ's" with "ALJ's or attorney adjudicator's" to further provide that the Council's actions with respect to a request for review or escalation are the same for cases that were decided by or pending before an ALJ or an attorney adjudicator.

We received no comments on these proposals, other than: (1) Comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals

issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1108 and 423.2108 as proposed without modification.

**e. Council Reviews on Its Own Motion (§§ 405.1110 and 423.2110)**

As described below, we proposed several changes to §§ 405.1110 and 423.2110, which discuss Council reviews on its own motion. 81 FR 43790, 43848–43849. Current §§ 405.1110(a) and 423.2110(a) state the general rule that the Council may decide on its own motion to review a decision or dismissal issued by an ALJ, and CMS or its contractor, including the IRE, may refer a case to the Council within 60 calendar days after the date of the ALJ's decision or dismissal (for § 405.1110(a) or after the ALJ's written decision or dismissal is issued (for § 423.2110(a)). Current §§ 405.1110(b) and 423.2110(b) provide the standards for CMS or its contractors to refer ALJ decisions and dismissals to the Council for potential review under the Council's authority to review ALJ decisions and dismissals on the Council's own motion, and require that a copy of a referral to the Council be sent to the ALJ whose decision or dismissal was referred, among others. Current §§ 405.1110(c) and 423.2110(c) explain the standards of review used by the Council in reviewing the ALJ's action. Current §§ 405.1110(d) and 423.2110(d) explain the actions the Council may take, including remanding the case to the ALJ for further proceedings, and state that if the Council does not act on a referral within 90 calendar days after receipt of the referral (unless the 90 calendar day period has been extended as provided in the respective subpart), the ALJ's decision or dismissal is binding (§ 405.1110(d) further specifies that the decision or dismissal is binding on the parties to the decision).

We proposed at §§ 405.1110 and 423.2110 to replace each instance of “at the ALJ level” with “at the OMHA level” and “ALJ proceedings” with “OMHA proceedings.” We stated in the proposed rule that we believe the standards for referral to the Council by CMS or its contractor would be the same regardless of whether the case was decided by an ALJ or an attorney

adjudicator, and that “at the OMHA level” and “OMHA proceedings” would reduce confusion in situations where the case was decided by an attorney adjudicator. We proposed at § 405.1110(b)(2) to replace the references to current § 405.1052(b) with references to § 405.1052(d) to reflect the structure of proposed § 405.1052, and also proposed to revise §§ 405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in § 405.1110(b)(2)) or CMS or the IRE (in § 423.2110(b)(2)(ii)) sends a copy of its referral to the OMHA Chief ALJ. We stated that the current requirement to send a copy of the referral to the ALJ is helpful in allowing OMHA ALJs to review the positions that CMS is advocating before the Council, but at times has caused confusion as to whether the ALJ should respond to the referral (there is no current provision that allows the Council to consider a statement in response to the referral). In addition, we stated that the proposed revision would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We also proposed at § 405.1110(b)(2) to replace “all other parties to the ALJ's decision” with “all other parties to the ALJ's or attorney adjudicator's action” and at § 405.1110(d) to replace “ALJ decision” with “ALJ or attorney adjudicator action” to encompass both decisions and dismissals issued by an ALJ or an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We stated in the proposed rule that we believe that parties to an ALJ's dismissal or an attorney adjudicator's decision or dismissal have the same right to receive a copy of another party's written exceptions to an agency referral as the parties to an ALJ's decision, and that an ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the action. We proposed to replace each remaining instance in §§ 405.1110 and 423.2110 of “ALJ” with “ALJ or attorney adjudicator,” “ALJ's decision or dismissal” with “ALJ's or attorney adjudicator's decision or dismissal,” “ALJ's decision” with “ALJ's or attorney adjudicator's decision or dismissal,” and “ALJ's action” with “ALJ's or attorney adjudicator's action.” We stated that these proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and

therefore CMS and its contractors would have the same right to refer attorney adjudicator decisions and dismissals to the Council, and the Council would have the authority to take the same actions and have the same obligations in deciding whether to review an attorney adjudicator's decision or dismissal on its own motion.

Finally, we proposed at § 423.2110(b)(1) to replace “material to the outcome of the claim” with “material to the outcome of the appeal” because unlike Part A and Part B, no “claim” is submitted for drug coverage under Part D.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received two comments on these proposals. The commenters both objected to the proposal to revise §§ 405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in § 405.1110(b)(2)) or CMS or the IRE (in § 423.2110(b)(2)(ii)) sends a copy of its referral for own motion review by the Council to the OMHA Chief ALJ, rather than the ALJ who issued the decision, as provided under current §§ 405.1110(b)(2) and 423.2110(b)(2)(ii). The commenters felt it would be more appropriate for notice of the Council's action to be provided to the Chief ALJ, as the Council may not accept the referral for own motion review, or may not agree with the reason(s) for the referral, and therefore the referral itself is not necessarily evidence of a training or policy clarification need.

*Response:* Current §§ 405.1110(b)(2) and 423.2110(b)(2)(ii) contain a requirement for CMS, or CMS or the IRE, to send a copy of its referral to the ALJ. As we explained above (and in section III.A.5.e of the proposed rule), we proposed to instead require that the copy of the referral be sent to the Chief ALJ because the current requirement has at times caused confusion about whether a response is required from the ALJ. The current requirement also makes it difficult to identify trends and training opportunities, because copies of the referrals are sent to individual ALJs rather than to one individual at OMHA or a centralized location. We stated in the proposed rule that sending copies of the referrals to the Chief ALJ would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We also believe sending a copy of the referral to the Chief ALJ would be administratively simpler for CMS or the IRE.

We understand the commenter's suggestion that the notice of the Council's action is a better measure to assess the need for possible training or policy clarifications. In practice, OMHA has a process in place to receive and review copies of all Council actions, such as decisions remanding, reversing, modifying, or affirming ALJ decisions and dismissals, and dismissals of requests for review and declinations of referrals for own motion review, and OMHA makes those available to all staff. However, due to the time lag between when a request for own motion review is filed and when the Council issues its action (which may be up to 90 days), we believe requiring CMS (under § 405.1110), or CMS or the IRE (under § 423.2110), to send a copy of its referral to OMHA, and specifically to the Chief ALJ, will help ensure OMHA is aware of any trends that may necessitate action or further research for possible training or policy clarifications as early as possible, with the understood caveat that a referral in and of itself is not a basis for training or policy clarification because, as the commenter suggests, the Council's action on the referral is needed to fully assess any needed training or policy clarifications.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 405.908 as proposed with the following modification. We are correcting a drafting error in proposed § 405.1110(b)(2) by removing two references to a "hearing decision" issued under § 405.1046(a) and replacing them with "decision," because § 405.1046(a) as finalized in this rule also addresses decisions issued by an ALJ or attorney adjudicator when a hearing is not held.

#### f. Content of Request for Review (§§ 405.1112 and 423.2112)

As described below, we proposed a number of changes to §§ 405.1112 and 423.2112, which discuss the content of a request for Council review. 81 FR 43790, 43849. Current § 405.1112(a) requires a request for Council review to contain the date of the ALJ's decision or dismissal order, if any, among other information. Current § 423.2112(a)(1) states that the request for Council review must be filed with the entity specified in the notice of the ALJ's action. Current §§ 405.1112(b) and 423.2112(b) state that the request for review must identify the parts of the ALJ action with which the party or enrollee, respectively, requesting review disagrees and explain why he or she disagrees with the ALJ's decision,

dismissal, or other determination being appealed. Current § 405.1112(b) provides an example that if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority. Current §§ 405.1112(c) and 423.2112(c) state that the Council will limit its review of an ALJ's action to those exceptions raised by the party or enrollee, respectively, in the request for review, unless the appellant is an unrepresented beneficiary or the enrollee is unrepresented.

We proposed at §§ 405.1112 and 423.2112 to replace "ALJ's decision or dismissal" with "ALJ's or attorney adjudicator's decision or dismissal," "ALJ action" with "ALJ's or attorney adjudicator's action," and "ALJ's action" with "ALJ's or attorney adjudicator's action." These revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore information on the attorney adjudicator's decision and dismissal must be included in the request for Council review, and the scope of the Council's review would be the same as for an ALJ's decision or dismissal.

Current § 405.1112(a) states that a request for Council review must be filed with the Council or appropriate ALJ hearing office. However, we stated in the proposed rule that this provision may cause confusion when read with current § 405.1106(a), which states that a request for review must be filed with the entity specified in the notice of the ALJ's action. In practice, OMHA notices of decision and dismissal provide comprehensive appeal instructions directing requests for Council review to be filed directly with the Council, and provide address and other contact information for the Council. Therefore, we proposed to revise § 405.1112(a) to state that the request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action, which would align § 405.1112(a) with current § 405.1106(a), and reaffirm that a request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

Current § 405.1112(a) also states that the written request for review must include the hearing office in which the appellant's request for hearing is pending if a party is requesting escalation from an ALJ to the Council. In light of the proposed revisions to the

escalation process discussed in section III.A.3.h.i of the proposed rule and II.B.3.h.i of this final rule above, we proposed to remove this requirement from § 405.1112(a) because proposed § 405.1016 would provide that a request for escalation is filed with OMHA. In accordance with proposed § 405.1016, if the request for escalation meets the requirements of § 405.1016(f)(1) and a decision, dismissal, or remand cannot be issued within 5 calendar days after OMHA receives the request, the appeal would be forwarded to the Council.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter requested clarification as to whether the criteria specified in § 405.1110 for agency referrals are also appropriate bases for requests for review.

*Response:* We clarify that appellants may file requests for Council review for any reason they disagree with the ALJ's decision or dismissal, including if they believe that the ALJ abused his or her discretion or that the decision or dismissal is not supported by the evidence. On the other hand, CMS or its contractors may refer cases to the Council only for the reasons specified in § 405.1110(b) and § 423.2110(b) (if CMS or a contractor believes that the ALJ's or attorney adjudicator's decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the public interest; or, where CMS or its contractor participated (or requested to participate, for Part D appeals) in the appeal at the OMHA level, then CMS is also permitted to refer cases to the Council on the additional bases that it believes the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of the evidence or the ALJ or attorney adjudicator abused his or her discretion).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1112 and 423.2112 as proposed without modification.

#### g. Dismissal of Request for Review (§§ 405.1114 and 423.2114)

We proposed at § 405.1114(c)(3) to replace "ALJ hearing" with "ALJ's or attorney adjudicator's action." This proposed revision would provide that the paragraph applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore a



valid and timely request for Council review filed by another party to an attorney adjudicator's decision or dismissal would preclude dismissal of a request for Council review under § 405.1114(c). We did not propose any corresponding changes to § 423.2114 (which we inadvertently referenced as § 423.1114 in the proposed rule) because there is no provision equivalent to current § 405.1114(c)(3). 81 FR 43790, 43849.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 405.1114 as proposed without modification.

#### h. Effect of Dismissal of Request for Council Review or Request for Hearing (§§ 405.1116 and 423.2116)

Current §§ 405.1116 and 423.2116 describe the effect of a dismissal by the Council of a request for Council review or a request for hearing. We proposed to replace "ALJ" with "ALJ or attorney adjudicator" to provide that the denial of a request for Council review of a dismissal issued by an attorney adjudicator is binding and not subject to judicial review in the same manner as the denial of a request for Council review of a dismissal issued by an ALJ. We stated in the proposed rule that we believe the Council's denial of a request to review an attorney adjudicator's dismissal would be subject to the same general rules described in sections III.A.3.c and III.A.3.x of the proposed rule and sections II.B.3.c and II.B.3.x of this final rule above pertaining to reviews of dismissals at the next adjudicative level, and that further review of the attorney adjudicator's dismissal in Federal district court would be unavailable. 81 FR 43790, 43849–43850.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or

appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1116 and 423.2116 as proposed without modification.

#### i. Obtaining Evidence From the Council (§§ 405.1118 and 423.2118)

As described below, we proposed several changes to §§ 405.1118 and 423.2118, which provide that a party or an enrollee, respectively, may request and receive a copy of all or part of the record of the ALJ hearing. 81 FR 43790, 43850. We proposed to replace "ALJ hearing" with "ALJ's or attorney adjudicator's action." We stated in the proposed rule that this proposed revision would provide that a party to an attorney adjudicator action, or to an ALJ decision that was issued without a hearing, may request and receive a copy of all or part of the record to the same extent as a party to an ALJ hearing. We also proposed to replace the reference to an "exhibits list" with a reference to "any index of the administrative record" to provide greater flexibility in developing a consistent structure for the administrative record. In addition, we proposed at § 405.1118 to replace the reference to a "tape" of the oral proceeding with an "audio recording" of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We proposed a parallel revision to § 423.2118 to replace the reference to a "CD" of the oral proceeding with an "audio recording" of the oral proceeding.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* One commenter asked that § 405.1118 be revised to clarify exactly where parties should direct their requests for a copy of all or part of the record of the ALJ hearing. The commenter stated that it has had difficulty obtaining copies of the record from the ALJ who conducted the hearing once OMHA had released custody of the record. The commenter thought it would be helpful if the notice of decision issued by OMHA contained language that informed the appellant where to send such requests.

*Response:* Proposed § 405.1118 is titled "Obtaining evidence from the Council," and deals with requests for copies of all or part of the record of the ALJ hearing. After a party requests review by the Council, the entire administrative record, including audio recordings, documentary evidence, and

any index of the administrative record, is transferred to the Council. Thus, parties who are requesting a copy of all or part of the record of the ALJ hearing after a request for review has been filed with the Council may direct their requests directly to the Council. For requests that are made prior to a request for review being filed with the Council, see the discussion in section II.B.3.t of this final rule above. With respect to the commenter's suggestion regarding including language in the notice of an ALJ's decision, we may consider the suggestion in future revisions to the standard notice.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1118 and 423.2118 as proposed without modification.

#### j. What Evidence May Be Submitted to the Council (§§ 405.1122 and 423.2122)

As described below, we proposed several changes to §§ 405.1122 and 423.2122, which describe the evidence that may be submitted to and considered by the Council, the process the Council follows in issuing subpoenas, the reviewability of Council subpoena rulings, and the process for seeking enforcement of subpoenas. 81 FR 43790, 43850. Current § 405.1122(a)(1) provides that the Council will limit its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, unless the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level. We proposed at § 405.1122(a) introductory text and (a)(1) to replace each instance of "ALJ's decision" with "ALJ's or attorney adjudicator's decision," "before the ALJ" with "before the ALJ or attorney adjudicator," and "the ALJ level" with "the OMHA level." We stated in the proposed rule that we believe the standard for review of evidence at the Council level would be the same regardless of whether the case was decided by an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), at the OMHA level. We also proposed corresponding revisions to § 423.2122(a) introductory text and (a)(1). Also, to help ensure it is clear that the exception for evidence related to new issues raised at the OMHA level is not limited to proceedings in which a hearing before an ALJ was conducted, we proposed at §§ 405.1122(a)(1) and § 423.2122(a)(1) to replace "hearing decision" with "ALJ's or attorney adjudicator's decision."

Current § 405.1122(a)(2) provides that if the Council determines that additional evidence is needed to resolve the issues in the case, and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. For the reasons described above, we proposed at § 405.1122(a)(2) to replace “ALJ” with “ALJ or attorney adjudicator” and “hearing record” with “administrative record,” along with corresponding revisions to § 423.2122(a)(2). Current § 405.1122(b)(1) describes the evidence that may be considered by the Council when a case is escalated from the ALJ level. For the reasons described above, we proposed to replace “ALJ level” with “OMHA level.” We did not propose any corresponding changes to § 423.2122 because escalation is not available for Part D coverage appeals. Finally, we proposed to replace all remaining instances of “ALJ” in § 405.1122(b)(1), (b)(2), (c)(2), (c)(3) introductory text, (c)(3)(i), and (c)(3)(ii) with “ALJ or attorney adjudicator,” as we believe the Council’s authority to consider evidence entered in the record by an attorney adjudicator and to remand a case to an attorney adjudicator for consideration of new evidence would be the same as the Council’s current authority to consider evidence entered in the record by an ALJ and remand a case to an ALJ. We did not propose any corresponding changes to § 423.2122 because there are no remaining references to “ALJ.”

We received no comments on these proposals, other than: (1) Comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1122 and 423.2122 as proposed without modification.

k. Case Remanded by the Council (§§ 405.1126 and 423.2126)

As described below, we proposed a number of changes to the regulations at §§ 405.1126 and 423.2126 concerning cases that are remanded by the Council. 81 FR 43790, 43850–43851. Current §§ 405.1126(a) and (b) explain the Council’s remand authority. We proposed to replace each instance of “ALJ” with “ALJ or attorney adjudicator” to provide that the Council may remand a case in which additional evidence is needed or additional action is required by the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). Proposed § 405.1126(b) would also provide that an ALJ or attorney adjudicator would take any action that is ordered by the Council, and may take any additional action that is not inconsistent with the Council’s remand order. We stated in the proposed rule that we believe it is necessary for the Council to have the same authority to remand an attorney adjudicator’s decision to the attorney adjudicator as the Council currently has to remand an ALJ’s decision to the ALJ, and that the attorney adjudicator’s actions with respect to the remanded case should be subject to the same requirements as an ALJ’s actions under the current provisions. We also proposed corresponding revisions to § 423.2126(a)(1) and (a)(2). Current §§ 405.1126(c) and (d) describe the procedures that apply when the Council receives a recommended decision from the ALJ, including the right of the parties to file briefs or other written statements with the Council. Because we proposed in § 405.1126(a) for the Council to have the same authority to order an attorney adjudicator to issue a recommended decision on remand as the Council currently has to order an ALJ to issue a recommended decision, we also proposed at § 405.1126(c) and (d) to replace “ALJ” with “ALJ or attorney adjudicator” to provide that the provisions apply to attorney adjudicators to the same extent as the provisions apply to ALJs, along with corresponding revisions to § 423.2126(a)(3) and (a)(4). Finally, current § 405.1126(e)(2) provides that if the Council determines more evidence is required after receiving a recommended decision, the Council may again remand the case to an ALJ for further development and another decision or recommended decision. Because we believe the Council should have the same authority to remand a case to an attorney adjudicator

following receipt of a recommended decision, we proposed at § 405.1126(e)(2) to replace “ALJ” with “ALJ or attorney adjudicator,” along with a corresponding revision to § 423.2126(a)(5)(ii), and to insert “if applicable” after rehearing because a rehearing may not be applicable in every circumstance (for example, where an attorney adjudicator issued a recommended decision and the Council does not remand with instructions to transfer the appeal to an ALJ for a hearing).

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1126 and 423.2126 as proposed without modification.

l. Action of the Council (§§ 405.1128 and 423.2128)

Current §§ 405.1128 and 423.2128 explain the actions the Council may take after reviewing the administrative record and any additional evidence (subject to the limitations on Council consideration of additional evidence). We proposed at §§ 405.1128(a) and 423.2128(a) to replace “ALJ” with “ALJ or attorney adjudicator,” which would provide that the Council may make a decision or remand a case to an ALJ or to an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). We stated in the proposed rule that we believe the Council should have the same authority to remand a case to an attorney adjudicator as the Council currently has to remand a case to an ALJ. Also, to help ensure there is no confusion that Council actions are not limited to proceedings in which a hearing before an ALJ was conducted, we proposed at §§ 405.1128(b) and 423.2128(b) to replace “the ALJ hearing decision” with “the ALJ’s or attorney adjudicator’s decision.” 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and

to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1128 and 423.2128 as proposed without modification.

m. Request for Escalation to Federal Court (§ 405.1132)

Current § 405.1132 explains the process for an appellant to seek escalation of an appeal (other than an appeal of an ALJ dismissal) from the Council to Federal district court if the Council does not issue a decision or dismissal or remand the case to an ALJ within the adjudication time frame specified in § 405.1100, or as extended as provided in subpart I. We proposed at § 405.1132 to replace each instance of “ALJ” with “ALJ or attorney adjudicator.” We stated in the proposed rule that these revisions would provide that the appellant may request that escalation of a case, other than a dismissal issued by an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to Federal district court if the Council is unable to issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within an applicable adjudication time frame, and that appellants may file an action in Federal district court if the Council is not able to issue a decision, dismissal, or remand to the ALJ or attorney adjudicator within 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period. We did not propose any corresponding changes to part 423, subpart U, as there is no equivalent provision because there are no escalation rights for Part D coverage appeals. 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 405.1132 as proposed without modification.

n. Judicial Review (§§ 405.1136, 423.1976, and 423.2136)

Current §§ 405.1136, 423.1976, and 423.2136 set forth the right to file a request for judicial review in Federal district court of a Council decision (or of an ALJ’s decision if the Council declines review as provided in § 423.1976(a)(1)). Current § 405.1136 also provides that judicial review in Federal district court may be requested if the Council is unable to issue a decision, dismissal, or remand within the applicable time frame following an appellant’s request for escalation. In addition, current §§ 405.1136 and 423.2136 specify the requirements and procedures for filing a request for judicial review, the Federal district court in which such actions must be filed, and describe the standard of review. We proposed at §§ 405.1136, 423.1976, and 423.2136 to replace each instance of “ALJ” with “ALJ or attorney adjudicator,” and “ALJ’s” with “ALJ’s or attorney adjudicator’s” to help ensure that there is no confusion that appellants may file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above) (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available for ALJ actions (or Council actions following an action by an ALJ). 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1136, 423.1976, and 423.2136 as proposed without modification.

o. Case Remanded by a Federal Court (§§ 405.1138 and 423.2138)

Current §§ 405.1138 and 423.2138 set forth the actions the Council may take when a Federal district court remands a case to the Secretary for further consideration. We proposed at §§ 405.1138 and 423.2138 to replace “ALJ” with “ALJ or attorney adjudicator” to provide that when a case is remanded by a Federal district court

for further consideration by the Secretary, the Council may remand the case to an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to issue a decision, take other action, or return the case to the Council with a recommended decision. 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1138 and 423.2138 as proposed without modification.

p. Council Review of ALJ Decision in a Case Remanded by a Federal District Court (§§ 405.1140 and 423.2140)

Current §§ 405.1140 and 423.2140 set forth the procedures that apply when a case is remanded to the Secretary for further consideration, and the Council subsequently remands the case to an ALJ, including the procedures for the Council to assume jurisdiction following the decision of the ALJ on its own initiative or upon receipt of written exceptions from a party or the enrollee. We proposed to replace each instance of “ALJ” throughout §§ 405.1140 and 423.2140 with “ALJ or attorney adjudicator” and to replace the reference to “ALJ’s” at §§ 405.1140(d) and 423.2140(d) with “ALJ’s or attorney adjudicator’s.” We stated in the proposed rule that these revisions would provide that the Council may remand these cases to the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), following remand from a Federal district court, and that the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand unless the Council assumes jurisdiction. We stated that these revisions would further apply the rules set forth in this section to cases reviewed by an attorney adjudicator as well as an ALJ. As described above in relation to the Council’s general remand authority under §§ 405.1126 and 423.2126, we stated that we believe it is necessary for the Council to have the same authority to remand an attorney

adjudicator's decision to the attorney adjudicator as the Council currently has to remand an ALJ's decision to the ALJ, and that would include cases that are remanded by a Federal district court to the Secretary for further consideration. 81 FR 43790, 43851–43852.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 405.1140 and 423.2140 as proposed without modification.

### *C. Specific Provisions of Part 405, Subpart J Expedited Reconsiderations*

In accordance with section 1869(b)(1)(F) of the Act, current § 405.1204 provides for expedited QIC reconsiderations of certain QIO determinations related to provider-initiated terminations of Medicare-covered services and beneficiary discharges from a provider's facility. Current § 405.1204(c)(4)(iii) explains that the QIC's initial notification may be done by telephone followed by a written notice that includes information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, and current § 405.1204(c)(5) provides that if the QIC does not issue a decision within 72 hours of receipt of the request for a reconsideration, the case can be escalated to the "ALJ hearing level." For consistency with part 405, subpart I, and to explain the rules that apply to an ALJ hearing, we proposed at § 405.1204(c)(4)(iii) and (c)(5) to amend these references to convey that a QIC reconsideration can be appealed to, or a request for a QIC reconsideration can be escalated to OMHA for an ALJ hearing in accordance with part 405, subpart I. We stated in the proposed rule that we believed these revisions would explain where a request for an ALJ hearing is directed from a subpart J proceeding, and the rules that would be applied to the request for an ALJ hearing following the QIC's reconsideration or escalation of the request for a QIC reconsideration. 81 FR 43790, 43852.

Current § 405.1204(c)(5) states that the beneficiary has a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after

the QIO determination is \$100 or more. However, this is inconsistent with the amount in controversy specified in section 1869(b)(1)(E) of the Act. We proposed to revise § 405.1204(c)(5) to provide that there is a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006. We stated in the proposed rule that we believed that this is more consistent with section 1869(b)(1)(E) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than \$100, as adjusted annually after 2004, which is implemented in § 405.1006, and would bring consistency to the amounts in controversy required for an escalation under subpart J and subpart I. 81 FR 43790, 43852.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on this proposal. The commenter supported the revision of § 405.1204(c)(5) to align the amount in controversy with section 1869(b)(1)(E) of the Act and § 405.1006.

*Response:* We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 405.1204 as proposed without modification.

### *D. Specific Provisions of Part 422, Subpart M*

#### 1. General Provisions (§ 422.562)

Current § 422.562(c)(1)(ii) states that if an enrollee receives immediate QIO review of a determination of non-coverage of inpatient hospital care, the QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of title 42, chapter IV. However, we stated in the proposed rule that we believe this provision is an outdated reference that has been superseded by current § 422.622, which provides for requesting immediate QIO review of the decision to discharge an enrollee from an inpatient hospital setting and appeals of that review as described under part 422, subpart M. The regulatory provisions at § 422.622 describe the processes for QIO review of the decision to discharge an MA enrollee from the inpatient hospital setting. Section 422.622 also explains the availability of other appeals processes if the enrollee does not meet the deadline for an immediate QIO

review of the discharge decision. These part 422, subpart M provisions govern the review processes for MA enrollees disputing discharge from an inpatient hospital setting. As noted above, we stated in the proposed rule that we believe the references to the procedures in parts 476 and 478 at § 422.562(c)(1)(ii) are obsolete. Therefore, we proposed to delete § 422.562(c)(1) to remove the outdated reference in current § 422.562(c)(1)(ii) and consolidate current (c)(1) and (c)(1)(i) into proposed (c)(1). 81 FR 43790, 43852.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 422.562 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we are also finalizing revisions to § 422.562(d). In section II.A.3 of this final rule above, we discuss our proposal to revise § 422.562(d), the comments we received related to this proposal, and the revisions we are finalizing to § 422.562(d) in this rule.

#### 2. Notice of Reconsidered Determination by the Independent Entity (§ 422.594)

Current § 422.594(b)(2) requires the notice of the reconsideration determination by an IRE to inform the parties of their right to an ALJ hearing if the amount in controversy is \$100 or more, if the determination is adverse (does not completely reverse the MAO's adverse organization determination). We proposed at § 422.594(b)(2) to amend this requirement so that the notice informs the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600, which in turn refers to the part 405 computation of the amount in controversy. We stated in the proposed rule that we believed this would increase accuracy in conveying when a party has a right to an ALJ hearing, and would be more consistent with section 1852(g)(5) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than \$100, as adjusted annually in accordance with section 1869(b)(1)(E)(iii) of the Act, which is implemented in part 405 at § 405.1006. 81 FR 43790, 43852. We discuss our proposed changes to § 405.1006 in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed

rule, we are finalizing the changes to § 422.594 as proposed without modification.

### 3. Request for an ALJ Hearing (§ 422.602)

Current § 422.602(b) provides that a party must file a request for an ALJ hearing within 60 days of the date of the notice of the IRE's reconsidered determination. However, in similar appeals brought under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002, a request for an ALJ hearing must be filed within 60 calendar days of receipt of a notice of reconsideration. We proposed at § 422.602(b)(1) to align the part 422 time frame for filing a request for an ALJ hearing with provisions for similar appeals under Medicare Part A and Part B, and Part D. We proposed that a request for an ALJ hearing would be required to be filed within 60 calendar days of receiving the notice of a reconsidered determination, except when the time frame is extended by an ALJ or, as proposed, attorney adjudicator, as provided in part 405. To provide consistency for when a notice of a reconsidered determination is presumed to have been received, we proposed at § 422.602(b)(2) that the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary, which is the same presumption that is applied to similar appeals under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002. 81 FR 43790, 43852–43853.

Provided below are summaries of the specific comments received and responses to these comments:

*Comment:* We received two comments on this proposal. One commenter supported revising § 422.602(b) to state in paragraph (b)(1) that a request for hearing must be filed within 60 calendar days of receipt of the notice of a reconsidered determination, rather than 60 calendar days of the date of the notice. The other commenter also supported this proposed revision, as well as the proposal to create a presumption at § 422.602(b)(2) that the date of receipt of the reconsideration is 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary. The commenter expressed that the current inconsistency between § 422.602(b) and the part 405, subpart I rules has caused problems for beneficiaries, providers, and ALJs, and supported our efforts to standardize the time frames for requesting an ALJ hearing.

*Response:* We thank both commenters for their support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 422.602 as proposed without modification.

### 4. Medicare Appeals Council (Council Review) (§ 422.608)

Current § 422.608 provides that any party to the hearing, including the MAO, who is dissatisfied with the ALJ hearing decision may request that the Council review the ALJ's decision or dismissal. We stated in the proposed rule that we believed that the reference to a "hearing" or "hearing decision," in the first instance, then "decision or dismissal" in the second instance, may cause confusion regarding a party's right to request Council review. We proposed at § 422.608 that any party (including the MAO) to the ALJ's or, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), attorney adjudicator's decision or dismissal, who is dissatisfied with the decision or dismissal, may request that the Council review that decision or dismissal. We stated in the proposed rule that we believed this would resolve any potential confusion regarding a party's right to request Council review of a decision when a hearing was not conducted and a dismissal of a request for hearing, and further provide that the section applies to decisions and dismissals issued by an attorney adjudicator. Therefore, we proposed to revise § 422.608 to provide that a request for Council review may be filed by a party (including the MAO) if he or she is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to § 422.608 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we also are revising

§ 422.608 to include a cross reference to § 422.562(d)(2).

### 5. Judicial Review (§ 422.612)

Current § 422.612 provides the circumstances under which a party may request judicial review of an ALJ or Council decision, and directs appellants to the procedures in part 405 for filing a request for judicial review. We proposed at § 422.612(a) to replace each instance of "ALJ's" with "ALJ's or attorney adjudicator's". Thus, we proposed in § 422.612(a) that appellants would be able to file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above) (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available under § 412.622(a) for ALJ actions (or Council actions following an action by an ALJ). 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 422.612 as proposed without modification.

### 6. Reopening and Revising Determinations and Decisions (§ 422.616)

Current § 422.616(a) provides that the determination or decision of an MA organization, independent entity, ALJ, or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, subject to the rules in part 405. We proposed at § 422.616(a) to replace "ALJ" with "ALJ or attorney adjudicator." As described in section III.A.2.1 of the proposed rule and II.B.2.1 of this final rule above with respect to §§ 405.980, 405.982, 405.984, 423.1980, 423.1982, and 423.1984, we believe it is necessary for an attorney adjudicator to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ may reopen the ALJ's decision under the current rules, and the action should be subject to the same limitations and requirements, and have the same effects

as an ALJ's action under these provisions. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 422.616 as proposed without modification.

#### 7. How an MA Organization Must Effectuate Standard Reconsideration Determinations and Decisions, and Expedited Reconsidered Determinations (§§ 422.618 and 422.619)

Current § 422.618(c)(1) and (c)(2) provide instructions for effectuation of decisions issued by an ALJ, or at a higher level of appeal, that reverse an IRE's decision on a standard reconsidered determination or decision. We proposed to replace "ALJ" with "ALJ or attorney adjudicator" at § 422.618(c)(1) and to make corresponding changes to § 422.619(c)(1) for decisions that reverse an IRE's decision on an expedited reconsidered determination or decision. We stated in the proposed rule that we believe the process for effectuating the decision of an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), should be the same as the process for effectuating the decision of an ALJ. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 422.618 and 422.619 as proposed without modification.

#### 8. Requesting Immediate QIO Review of the Decision To Discharge From the Inpatient Hospital and Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§§ 422.622 and 422.626)

In accordance with section 1852(g)(3) and (g)(4) of the Act, current §§ 422.622 and 422.626 provide for reviews of QIO determinations and expedited IRE reconsiderations of certain QIO determinations related to terminations of covered provider services furnished by home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) to an MA enrollee, and MA enrollee discharges from an inpatient hospital. Current § 422.622(g) provides that if an enrollee is still an inpatient in the hospital after a QIO determination reviewing a provider discharge from a hospital, the enrollee may request an IRE reconsideration of the QIO determination in accordance with § 422.626(g); and if an enrollee is no longer an inpatient in the hospital, the enrollee may appeal the QIO determination to an ALJ. Current § 422.626(g)(3) provides that if the IRE reaffirms its decision to terminate covered provider services furnished by an HHA, SNF, or CORF in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ. We proposed at §§ 422.622(g)(2) and 422.626(g)(3) to amend these references to provide that the appeal is made to OMHA for an ALJ hearing. We stated in the proposed rule that we believed these revisions would clarify where a request for an ALJ hearing is directed. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§ 422.622 and 422.626 as proposed without modification.

#### *E. Specific Provisions of Part 478, Subpart B*

##### 1. Applicability and Beneficiary's Right to a Hearing (§§ 478.14 and 478.40)

Current § 478.14(c)(2) explains that for the purposes of part 478 reconsideration and appeals, limitation of liability determinations on excluded coverage of certain services are made

under section 1879 of the Act, and initial determinations under section 1879 of the Act and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G for determinations under Medicare Part A, and part 405, subpart H for determinations under Medicare Part B. In addition, current § 478.40 states that an ALJ hearing may be obtained from the SSA Office of Hearings and Appeals, and the provisions of subpart G of 42 CFR part 405 apply unless they are inconsistent with the specific provisions of subpart B of 42 CFR part 478. We stated in the proposed rule that these references are outdated. Since §§ 478.14 and 478.40 were last updated in 1999, section 931 of the MMA transferred responsibility for the ALJ hearing function from SSA to HHS, and HHS established OMHA in 2005, to administer the ALJ hearing function, including ALJ hearings conducted under titles XI and XVIII of the Act (see 70 FR 36386). In addition, BIPA and the MMA established new appeal procedures that were implemented in 2005, at 42 CFR part 405, subpart I (70 FR 11420), and the portions of subparts G and H that previously applied to part 478, subpart B appeals were removed in 2012 (77 FR 29002). We proposed in §§ 478.14 and 478.40 to replace the current outdated references to part 405, subparts G and H, with references to part 405, subpart I. We also proposed in § 478.40 to update the reference to the entity with responsibility for the ALJ hearing function by replacing the SSA Office of Hearings and Appeals with OMHA. 81 FR 43790, 43854.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§ 478.14 and 478.40 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we are also finalizing revisions to § 478.40(c). In section II.A.3 of this final rule above, we discuss our proposal to revise § 478.40(c), the comments we received related to this proposal, and the revisions we are finalizing to § 478.40(c) in this rule.

##### 2. Submitting a Request for a Hearing (§ 478.42)

Similar to current § 478.40, as discussed above, current § 478.42(a) has outdated references to SSA offices that are no longer involved in the Medicare claim appeals process. In addition, current § 478.42(a) permits beneficiaries to file requests for an ALJ hearing with other entities, which could cause significant delays in obtaining a hearing

before an OMHA ALJ. We proposed in § 478.42(a) to direct beneficiaries to file a request for an ALJ hearing with the OMHA office identified in the QIO's notice of reconsidered determination. This revision would be clearer for beneficiaries, who are provided with appeal instructions by the QIOs, and reduce delays in obtaining a hearing by an OMHA ALJ. 81 FR 43790, 43854.

Current § 478.42(b) requires that a request for hearing is filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination and the date of receipt is assumed to be 5 days after the date on the notice unless there is a reasonable showing to the contrary. Current § 478.42(b) also provides that a request is considered filed on the date it is postmarked. To align part 478, subpart B with procedures for requesting an ALJ hearing under part 405, subpart I; part 422, subpart M; and part 423, subpart U, we proposed in § 478.42(b) to provide that the request for hearing must be filed within 60 "calendar" days of receiving notice of the QIO reconsidered determination and that the notice is presumed to be received 5 "calendar" days after the date of the notice. In addition, to further align the part 478, subpart B procedures for requesting an ALJ hearing with the other parts, we proposed in § 478.42(c) to amend the standard to demonstrate that notice of QIO reconsidered determination was not received within 5 calendar days by requiring "evidence" rather than the current "reasonable showing," and also to revise when a request is considered filed, from the date it is postmarked to the date it is received by OMHA. These changes would create parity with requests for hearing filed by beneficiaries and enrollees for similar services but under other parts of title 42, chapter IV. 81 FR 43790, 43854.

Provided below is a summary of the specific comment received and our response to this comment:

*Comment:* We received one comment on these proposals. The commenter asked whether there was an inconsistency in calculating time for transport of mail from the QIO to the appellant, as compared to mail from the appellant to OMHA. The commenter questioned why five calendar days were allowed for transport from the date on the QIO notice, while zero days were allowed on top of the statutory 60-day filing period for transport of the request for hearing from the appellant.

*Response:* Proposed § 478.42(b) revises when a request is considered filed, from the date it is postmarked to the date it is received by OMHA, to create parity with requests for hearing

and reviews of dismissals filed by beneficiaries and enrollees for similar services but under part 405, subpart I; part 422, subpart M; and part 423, subpart U, all of which consider a request to be filed on the date it is received by OMHA. For notices sent from the QIO to the appellant, the regulation presumes a mailing time of five calendar days to account for the time it takes to receive the notice through regular mail. However, as is currently required for appellants under part 405, subpart I; part 422, subpart M; and part 423, subpart U, we proposed that appellants filing requests for hearing and reviews of dismissals under part 478, subpart B would now be required to mail requests with sufficient time for the requests to be received by OMHA no later than the 60th day after receiving the QIO's reconsidered determination.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 478.42 as proposed without modification.

### 3. Determining the Amount in Controversy (§ 478.44)

Current § 478.44(a) explains how the amount in controversy for an ALJ hearing is determined in part 478, subpart B hearings. Current § 478.44(a) has outdated references to §§ 405.740 and 405.817 from part 405, subparts G and H respectively, for calculating the amount in controversy for an individual appellant or multiple appellants. In 2012, subpart G was removed and subpart H was significantly revised and no longer applies to Medicare claim appeals (77 FR 29002). To update these reference to the current part 405 rules, we proposed in § 478.44(a) to replace the outdated cross-references for calculating the amount in controversy with references to § 405.1006(d) and (e), which describe the calculation for determining the amount in controversy and the standards for aggregating claims by an individual appellant or multiple appellants. 81 FR 43790, 43854. We discuss our proposed changes to § 405.1006 in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above.

Current § 478.44(b) and (c) explain that if an ALJ determines the amount in controversy is less than \$200, the ALJ, without holding a hearing, notifies the parties to the hearing, and if a request for hearing is dismissed because the amount in controversy is not met, a notice will be sent to the parties to the hearing. However, when a request for hearing is dismissed because the

amount in controversy is not met, no hearing is conducted and the parties to the proceedings are the same regardless of whether a hearing was conducted. To prevent potential confusion, we proposed in § 478.44(b) and (c) to replace "parties to the hearing" with "parties" so it is understood that they are parties regardless of whether a hearing is conducted. Because an attorney adjudicator would have to determine whether appeals assigned to him or her, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), meet the amount in controversy requirement, we also proposed at § 478.44(a) and (b) that an attorney adjudicator may determine the amount in controversy, and may determine that the amount in controversy is less than \$200 and notify the parties to submit additional evidence to prove that the amount in controversy is at least \$200. However, because we did not propose authority for an attorney adjudicator to dismiss a request for an ALJ hearing because the amount in controversy is not met, we proposed in § 478.44(c) that in cases where an attorney adjudicator has requested that the parties submit additional evidence related to the amount in controversy, an ALJ would dismiss the request for hearing if at the end of the 15-day period to submit additional evidence to prove that the amount in controversy is at least \$200, the ALJ determines that the amount in controversy is less than \$200. 81 FR 43790, 43854.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 478.44 as proposed without modification.

### 4. Medicare Appeals Council and Judicial Review (§ 478.46)

Current § 478.46(a) states that the Council will review an ALJ's hearing decision or dismissal under the same circumstances as those set forth at 20 CFR 404.970, which is now an outdated reference to SSA Appeals Council procedures for Council review. We proposed at § 478.46(a) to replace the outdated reference to 20 CFR 404.970



with references to current §§ 405.1102 (“Request for Council review when ALJ or attorney adjudicator issued a decision or dismissal”) and 405.1110 (“Council reviews on its own motion”). In addition, we proposed in § 478.46(a) and (b) to replace “hearing decision” with “decision,” and “ALJ” with “ALJ or attorney adjudicator” because hearings are not always conducted and a decision can generally be appealed regardless of whether a hearing was conducted, and attorney adjudicators may issue decisions or dismissals for which Council review may be requested, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43855.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 478.46 as proposed without modification.

#### 5. Reopening and Revision of a Reconsidered Determination or a Decision (§ 478.48)

The title of current § 478.48 references reopenings and revisions of reconsidered determinations and hearing decisions, and current § 478.48 has an outdated reference to subpart G of 42 CFR part 405 for the procedures for reopening a decision by an ALJ or the DAB.

We proposed to revise the title of § 478.48 to replace “hearing decision” with “decision,” and in proposed paragraphs (b) and (c) to replace “ALJ” with “ALJ or attorney adjudicator” so the provision is understood to apply to decisions by ALJs, regardless of whether a hearing was conducted, or, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), attorney adjudicators, as well as review decisions, which are conducted by the Council at the DAB. We also proposed at § 478.48(b) to replace the outdated reference to § 405.750(b), which was part of the now removed part 405, subpart G (77 FR 29016 through 29018), with § 405.980, which is the current part 405, subpart I reopening provision. 81 FR 43790, 43855.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to § 478.48 as proposed without modification.

#### F. Effective Date and Applicability of the Provisions of the Final Rule

In accordance with 5 U.S.C. 553(d) and section 1871 of the Act, publication of a final rule may be made not less than 30 days before its effective date. We are making this final rule effective 60 days after publication in the **Federal Register** to provide appellants, other parties and potential parties and participants, and those who adjudicate appeals with additional time to make any necessary changes to comply with the provisions of the final rule.

Although we did not solicit comment on the effective date of the final rule, we did receive one comment on the subject. Provided below is a summary of that comment, along with our response to the comment and further details about the effective date and applicability of the final appeals provisions.

*Comment:* One commenter requested that the final rule not be made effective for Part D plan sponsors prior to the next contract year that is at least six months after the published effective date of the final rule. The commenter believed this additional time would be necessary to allow time for CMS to issue implementation guidance and for plans and pharmacy benefit managers to revise policies and documentation to describe the revised appeals procedures to enrollees.

*Response:* We do not believe further delaying the effective date of this rule for Part D plan sponsors is necessary. Part D plan sponsors will have 60 days from publication before the provisions of the final rule become effective. In addition, the changes we are finalizing relate primarily to the OMHA level of appeal. We proposed no changes to the part 423, subpart M rules governing Part D plan sponsor coverage determinations, redeterminations, or reconsiderations by an IRE, other than minor conforming edits associated with our attorney adjudicator proposal and the proposal to replace references to

“MAC” with “Council.” We expect that enrollees will continue to receive information about the OMHA level of appeal in the notice of the IRE’s reconsideration, and therefore we believe it is unnecessary to allow additional time for Part D plan policies and documentation to be updated to inform beneficiaries of the changes in the final rule.

While the provisions of this final rule are effective with the effective date of this final rule, we recognize that there is currently a large volume of pending appeals at the OMHA and Council levels that were filed before the effective date of the final rule and are at various stages of the adjudication process, and it may be unclear how these final provisions will apply in those instances—and in a manner that avoids retroactive application. The provisions of this final rule will apply prospectively to all appeals, but specific provisions will not be applied to pending appeals filed before the effective date of the final rule in which certain actions or stages of the appeals process have already taken place prior to the effective date. For example, a revised requirement regarding the contents of a request for hearing is effective with the effective date of this final rule, but the requirement would not be applicable in a pending appeal if the hearing request was already filed prior to the effective date of this final rule (that is, the hearing request would not have to be re-filed to include the new contents of the request finalized in this rule). But for other appeals that are pending prior to the effective date of this final rule, provisions of this final rule may be applicable if a particular action or procedural step in those appeals has not yet taken place (for example, a revised final requirement regarding scheduling and sending notice of a hearing would apply if the hearing has not yet been scheduled and the notice of hearing has not yet been sent in a pending appeal).

Accordingly, the revised appeal procedures of this final rule are effective on the effective date of the final rule for all appeals filed on or after the effective date of the final rule, and appeals that were filed, but not decided, dismissed or remanded, prior to the effective date of the final rule. However, with regard to appeals that were filed, but not decided, dismissed or remanded, prior to the effective date of the final rule, we have provided a list of provisions in the table below as examples to help clarify how the revised rules will apply depending upon whether certain actions or procedures in such appeals have taken place as of the effective date of the

final rule. This guidance clarifying the application of certain provisions will help ensure pending appeals continue to move forward in the appeals process, and avoid retroactive application of the revised appeal provisions when certain

actions or stages of the appeals process took place prior to the effective date of this final rule. We will provide additional guidance in the future, as necessary, to assist appellants and other parties, as well as OMHA and the

Council, in regards to the application of the revised appeals procedures for appeals that were pending prior to the effective date of the final rule.

APPLICATION OF CERTAIN FINAL APPEALS PROVISIONS FOR APPEALS THAT WERE FILED BUT NOT DECIDED, DISMISSED, OR REMANDED PRIOR TO THE EFFECTIVE DATE OF FINAL RULE

Section(s)	Applicability
§ 405.910(d)(3) .....	Not applicable (any applicable time frame will not be impacted if an appointment of representative is defective).
§ 405.910(l) .....	Applicable to delegations of an appointment of representation that are made on or after the effective date of the final rule.
§ 405.990 .....	Applicable to requests for expedited access to judicial review filed on or after the effective date of the final rule.
§ 405.1000(e) .....	Applicable to for waivers of the right to appear filed on or after the effective date of the final rule.
§ 405.1006(e) .....	Not applicable (the provisions of the rules related to aggregating claims to meet the amount in controversy in effect at the time the request for hearing or request for review of a QIC dismissal was filed (current § 405.1006(e) continue to apply).
§ 405.1010, § 405.1012 .....	Applicable to elections to participate in the proceedings on a request for an ALJ hearing and elections for party status made on or after the effective date of the final rule.
§ 405.1014(a) .....	Not applicable (the provisions of the rules related to the content of the request in effect at the time the request for hearing was filed (current § 405.1014(a) continue to apply).
§ 405.1016(f) .....	Applicable to requests for escalation filed on or after the effective date of the final rule.
§ 405.1020–§ 405.1024 .....	Applicable to hearings that are scheduled or re-scheduled on or after the effective date of the final rule, regardless of when the hearing is scheduled to occur.
§ 405.1028 .....	Applicable to reviews of evidence submitted by parties that occur on or after the effective date of the final rule.
§ 405.1030 .....	Applicable to hearings that occur on or after the effective date of the final rule.
§ 405.1032(a)–(c) .....	Applicable unless a hearing was scheduled or re-scheduled before the effective date of the final rule, regardless of when the hearing is scheduled to occur.
§ 405.1032(d) .....	Not applicable (the provisions of the rules related to appeals involving statistical sampling and extrapolations in effect at the time the request for hearing was filed (current § 405.1064) continue to apply).
§ 405.1038(b)(1)(i) .....	Applicable to waivers of the right to appear filed on or after the effective date of the final rule.
§ 405.1038(b)(1)(ii) .....	Not applicable (the provisions of the rules related to whether the ALJ may decide a case on the record and not conduct a hearing when the appellant lives outside of the United States in effect at the time the request for hearing was filed (current § 405.1038(b)(1)(ii) continue to apply).
§ 405.1040 .....	Applicable to conferences scheduled on or after the effective date of the final rule, regardless of when the conferences are scheduled to occur.
§ 405.1042(a) .....	Applicable to requests for an ALJ hearing assigned to an ALJ or attorney adjudicator on or after the effective date of the final rule.
§ 405.1056(g) .....	Applicable to remands issued on or after the effective date of the final rule.
§ 405.1104 .....	Applicable to requests for escalation filed on or after the effective date of the final rule.
§ 423.1970(c) .....	Not applicable (the provisions of the rules related to aggregating claims to meet the amount in controversy in effect at the time the request for hearing or request for review of a QIC dismissal was filed (current § 423.1970(c) continue to apply).
§ 423.1990 .....	Applicable to requests for expedited access to judicial review filed on or after the effective date of the final rule.
§ 423.2000(e) .....	Applicable to waivers of the right to appear filed on or after the effective date of the final rule.
§ 423.2010 .....	Applicable to requests to participate in the proceedings on a request for an ALJ hearing made on or after the effective date of the final rule.
§ 423.2014(a) .....	Not applicable (the provisions of the rules related to the content of the request in effect at the time the request for hearing was filed (current § 423.2014(a) continue to apply).
§ 423.2020–§ 423.2024 .....	Applicable to hearings that are scheduled or re-scheduled on or after the effective date of the final rule, regardless of when the hearing is scheduled to occur.
§ 423.2030 .....	Applicable to hearings that occur on or after the effective date of the final rule.
§ 423.2032 .....	Applicable unless a hearing was scheduled or re-scheduled before the effective date of the final rule, regardless of when the hearing is scheduled to occur.
§ 423.2038(b)(1)(i) .....	Applicable to waivers of the right to appear filed on or after the effective date of the final rule.
§ 423.2038(b)(1)(ii) .....	Not applicable (the provisions of the rules related to whether the ALJ may decide a case on the record and not conduct a hearing when the appellant lives outside of the United States in effect at the time the request for hearing was filed (current § 423.2038(b)(1)(ii) continue to apply).
§ 423.2040 .....	Applicable to conferences scheduled on or after the effective date of the final rule, regardless of when the conferences are scheduled to occur.
§ 423.2042(a) .....	Applicable to requests for an ALJ hearing assigned to an ALJ or an attorney adjudicator on or after the effective date of the final rule.
§ 423.2056(g) .....	Applicable to remands issued on or after the effective date of the final rule.
§ 478.40(a) .....	Applicable to requests for an ALJ hearing filed on or after the effective date of the final rule.
§ 478.42 .....	Applicable to requests for an ALJ hearing filed on or after the effective date of the final rule.

### III. Comments Beyond the Scope of the Final Rule

In response to the proposed rule, some commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are generally not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information or recommendations in the comments. In a few instances, commenters captioned their comments indicating they were submitted in response to a particular proposal, but the comment was nevertheless outside the scope of the proposed rule. In these instances, we briefly summarized the comments in section II of this final rule above, in the appropriate subsection addressing the particular proposal.

### IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows:

- In response to public comment, we added the following language to § 401.109(a) to include the general criteria the DAB Chair may consider when selecting a Council decision as precedential: “In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.” We also added a parenthetical to indicate that the term “DAB Chair” is short for the Chair of the Department of Health and Human Services Departmental Appeals Board.

- For consistency with the rest of part 405, subpart I, and because the terms “ALJ” and “Council” are already defined in § 405.902, we removed “Administrative Law Judge (ALJ)” and “Medicare Appeals Council (Council)” from § 405.904(a)(1) and added “ALJ” and “Council” in their place, respectively.

- For consistency with § 405.1038, we removed language that we inadvertently included in § 405.1000(g) that is not consistent with the language in § 405.1038(a) as finalized in this rule. We revised § 405.1000(g) to state that “An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a

fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.”

- In response to public comment, we did not finalize our proposal at § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we did not finalize § 405.1006(d)(2)(i)(B) because, given that we did not finalize § 405.1006(d)(2)(i)(A), there was no longer a need to distinguish between items and services with and without a published Medicare fee schedule or contractor-priced amount. We also did not finalize proposed § 405.1006(d)(2) and (d)(2)(i) introductory text or proposed § 405.1006(d)(1) introductory text. Accordingly, we maintained the text of current § 405.1006(d)(1), except that we: (1) Added “In general” as a paragraph heading, as proposed; (2) replaced “for the items and services in question” with “for the items and services in the disputed claim” in § 405.1006(d)(1) introductory text, as proposed; and (3) replaced “Any deductible and coinsurance amounts applicable in the particular case” in current § 405.1006(d)(1)(ii) with “Any deductible and/or coinsurance amounts that may be collected for the items or services,” as proposed. In addition, we also did not finalize our proposal to revise and re-designate current § 405.1006(d)(2) as § 405.1006(d)(3), except for the proposal to add “Limitation on liability” as a paragraph heading. However, for consistency with paragraph (d)(1)(ii), as finalized, we replaced “any deductible and coinsurance amounts applicable in the particular case” in current § 405.1006(d)(2) with “any deductible and/or coinsurance amounts that may be collected for the items or services.” We also did not finalize proposed § 405.1006(d)(2)(ii) and (iii).

- We finalized proposed § 405.1006 paragraphs (d)(4), (5), (6), and (7) with the modifications discussed below, but re-designated them as paragraphs (d)(3), (4), (5), and (6), respectively, because we did not finalize proposed § 405.1006(d)(2) or re-designate current § 405.1006(d)(2) as § 405.1006(d)(3). We replaced “in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy” in paragraph (d)(3) (proposed paragraph (d)(4)) with “in accordance with paragraph (d)(1) of

this section, except that the amount charged to the individual.” In addition, we replaced “Notwithstanding paragraphs (d)(1) and (2) of this section” in paragraphs (d)(4), (5), and (6) (proposed paragraphs (d)(5), (6), and (7)) with “Notwithstanding paragraph (d)(1) of this section.”

- We corrected a drafting error in the text of proposed § 405.1010(c)(3)(i) by replacing “by within 14 calendar days” with “within 14 calendar days.”

- In response to public comment, we added a requirement in §§ 405.1010(c)(3)(ii), 405.1012(c)(2)(ii) and 423.2010(d)(3)(ii) that copies of position papers and/or written testimony (and for purposes of § 405.1012(c)(2)(ii), any evidence) submitted to OMHA must be sent to the other parties within the same time frames that apply to the submissions to OMHA.

- We added language to § 405.1010(d)(3) to provide that CMS or a contractor that is precluded from participating in the oral hearing may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with § 405.1012. In light of this change, we also made a corresponding revision to § 405.1010(c)(2) to state that when CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in § 405.1010(d)(3).

- We clarified in § 405.1012(a)(2) that an ALJ may not request that CMS and/or one or more of its contractors be a party to the hearing if the request for hearing was filed by an unrepresented beneficiary.

- In response to public comment, we did not finalize our proposals at §§ 405.1014(a)(1)(vii) and 423.2014(a)(1)(vii), which would have required that the request for hearing contain a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by OIG or other law enforcement agencies.

- In response to public comment, we did not finalize our proposal at § 405.1014(a)(1)(viii), which would have required that, for requests filed by providers, suppliers, Medicaid State agencies, applicable plans, or a beneficiary who is represented by a provider, supplier or Medicaid State agency, the request for hearing must include the amount in controversy applicable to the disputed claim determined in accordance with § 405.1006, unless the matter involves a provider or supplier termination of

Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services.

- We removed the term “entity office,” which was a drafting error, from proposed § 405.1014(c)(2) and added “office” in its place.

- We clarified §§ 405.1014(c)(2) and 423.2014(d)(2)(i) to state that if the request for hearing is timely filed with an office other than the office specified in the QIC’s reconsideration, the request is not treated as untimely.

- We revised 405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the potential consequences of failing to send a copy of the request, materials, and/or evidence or summary thereof to the other parties.

- We corrected a drafting error by adding a missing comma to § 423.2018(b)(1) and (c)(1) for consistency with § 405.1018(a) and to clarify that there are three time frames when a represented enrollee may submit written or other evidence he or she wishes to have considered: (1) With the request for hearing; (2) by the date specified in the request for hearing in accordance with § 423.2014(a)(2); or (3) if a hearing is scheduled, within 10 calendar days (or 3 calendar days for expedited Part D appeals) of receiving the notice of hearing.

- We revised § 405.1018(d) to provide in paragraph (d)(1) that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, and in (d)(2) that the requirement in paragraph (c) to support new evidence with a statement of good cause does not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

- We revised § 405.1020(c)(1) to state that the notice of hearing is also sent to CMS or any contractor that has elected to participate in the proceedings in accordance with § 405.1010(b).

- Because we proposed to adopt in § 423.2020(b)(2) the same revisions as in § 405.1020(b)(2), we revised § 423.2020(b)(2)(ii)(A) to state “video-conferencing and telephone technology are not available,” rather than “video-conferencing or telephone technology is not available,” for consistency with § 405.1020(b)(2)(ii)(A) as finalized.

- In response to public comment, we revised §§ 405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ

may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled.

- In response to public comment, we revised §§ 405.1030(b)(3) and 423.2030(b)(3) to clarify that a party or party’s representative (or enrollee or enrollee’s representative in the context of § 423.2030(b)(3)) may be excused from a hearing if that individual remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior.

- We revised §§ 405.1034(a)(1) and 423.2034(a)(1) to provide that OMHA will confirm whether an electronic copy of the redetermination or reconsideration is available in the official system of record prior to issuing a request for that information to the QIC or IRE and if so, will accept the electronic copy as the official copy. We also replaced “can only be provided by CMS, the IRE, and/or the Part D plan sponsor” in proposed § 423.2034(a)(1), which was a drafting error, with “can be provided only by CMS, the IRE, and/or the Part D plan sponsor,” for consistency with the definition in § 423.2034(a)(2).

- We revised § 405.1038(c) to provide that if the amount of payment is an issue before the ALJ or attorney adjudicator, a stipulated decision may be made if the statement from CMS or its contractor agrees to the amount of payment the party believes should be made. We made a corresponding change to § 423.2038(c) for stipulated decisions in part 423, subpart U proceedings.

- We revised § 405.1052(a)(7) and (b)(4) to provide that a request for hearing or a request for review of a QIC dismissal filed by an unrepresented beneficiary will not be dismissed if the appellant fails to send a copy of the request to the other parties in accordance with proposed § 405.1014(d).

- We revised §§ 405.1056(g) and 423.2056(g) to add language to specifically exempt remands that are issued on a review of a QIC’s or IRE’s dismissal of a request for reconsideration from potential review by the Chief ALJ or designee.

- We corrected a drafting error in proposed § 405.1110(b)(2) by removing two references to a “hearing decision” under § 405.1046(a) and replacing them with “decision,” because § 405.1046(a) as finalized in this rule also addresses

decisions issued by an ALJ or attorney adjudicator when a hearing is not held.

- We revised §§ 422.562(d) and 478.40(c) to specify in greater detail those part 405 provisions that implement specific sections of section 1869 of the Act that are not also included in sections 1852 and 1155 of the Act, and that we do not believe apply to part 422, subpart M or part 478, subpart B adjudications. Specifically, we are revising these regulations to provide that the following regulations in part 405, and any references thereto, do not apply to proceedings under part 422, subpart M or part 478, subpart B: (1) § 405.950 (time frames for making a redetermination); (2) § 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level); (3) § 405.1016 (time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council); (4) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b) and the time frame for the Council to decide an appeal of an ALJ’s or attorney adjudicator’s decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d); (5) § 405.1132 (request for escalation to Federal court); and (6) §§ 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other references to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

- We revised the second sentence of § 422.608 to reference § 422.562(d), such that this sentence states, “The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent they are appropriate, except as provided in § 422.562(d)(2).”

- For consistency with the title of part 423, subpart U as finalized, the revisions finalized related to attorney adjudicator reviews, and the revisions finalized to replace references to “MAC” with “Council,” we made technical conforming revisions to § 423.558(b) replace the reference to “MAC” with “Council” and the reference to “ALJ hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions.” We also made a technical edit to replace “Judicial review” with “judicial review.”

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The PRA exempts most of the information collection activities referenced in this final rule. In particular, the implementing regulations of the PRA at 5 CFR 1320.4 exclude collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party. Civil actions include administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment, or MAO organization determination or Part D plan sponsor coverage determination. However, one requirement contained in this final rule is subject to the PRA because the burden is imposed prior to an administrative action or denial of payment. This requirement is discussed below.

In summary, § 405.910 requires that when a provider or supplier is the party appointing a representative, the appointment of representation would include the Medicare National Provider Identifier (NPI) of the provider or supplier that furnished the item of service. Although this is a new regulatory requirement, the current Medicare Claims Processing Manual already states that the NPI should be included when a provider or supplier appoints a representative. The standardized form for appointing a representative, Form CMS-1696,

currently provides a space for the information in question. Importantly, this form is currently approved under OMB control number 0938-0950 and expires June 30, 2018.

The burden associated with this requirement is the time and effort of an individual or entity who is a provider or supplier to prepare an appointment of representation containing the NPI. As stated earlier, this requirement and the related burden are subject to the PRA; however, because we believe that this information is already routinely being collected, we estimate there would be no additional burden for completing an appointment of representative in accordance with § 405.910.

If you wish to view the standardized form and the supporting documentation, you can download a copy from the CMS Web site at <https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html>.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above.

If you wish to comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, HHS-2016-79, Fax: (202) 395-6974; or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

## VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have determined that the effect of this

final rule does not reach this economic threshold and thus is not considered a major rule. As detailed above, this final rule would only make minimal changes to the existing Medicare appeals procedures for claims for benefits under or entitlement to the original Medicare programs, and coverage of items, services, and drugs under the MA and voluntary Medicare prescription drug programs. Thus, this final rule would have negligible financial impact on beneficiaries and enrollees, providers or suppliers, Medicare contractors, MAOs, and Part D plan sponsors, but would derive benefits to the program and appellants.

HHS recognizes that the current appeals backlog is a matter of great significance, and it has made it a priority to adopt measures that are designed to reduce the backlog and improve the overall Medicare appeals process. To that end, HHS has initiated a series of measures, including this final regulation, that are aimed at both reducing the backlog and creating a more efficient Medicare appeals system.

We believe the changes in this regulation will help address the Medicare appeals backlog and create efficiencies at the ALJ level of appeal by allowing OMHA to reassign a portion of workload to non-ALJ adjudicators and reduce procedural ambiguities that result in unproductive efforts at OMHA and unnecessary appeals to the Medicare Appeals Council. In addition, the other changes, including precedential decisions and generally limiting CMS and CMS contractor participation or party status at the OMHA level unless the ALJ determines participation by additional entities is necessary for a full examination of the matters at issue (as provided in proposed §§ 405.1010(d) and 405.1012(d)), will collectively make the ALJ hearing process more efficient through streamlined and standardized procedures and more consistent decisions, and reduce appeals to the Medicare Appeals Council.

In particular, we are able to estimate the impact from one of the changes—the expansion of the pool of adjudicators. Based on FY 2016, and an assumption that future years are similar to FY 2016, we estimate that the expansion of the pool of adjudicators at OMHA could redirect approximately 24,500 appeals per year to attorney adjudicators who would be able to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload. If in future years the number of requests for hearing, waivers of oral hearing, requests for review of a contractor dismissal, or appellant

withdrawals of requests for hearing vary from FY 2016 data, then the number of appeals potentially addressed by attorney adjudicators would likely also vary.

In the proposed rule, we also estimated that the proposed modifications to calculating the amount in controversy required for an ALJ hearing could potentially remove appeals related to over 2,600 Part B low-value claims per year from the ALJ hearing process, after accounting for the likelihood of appellants aggregating claims to meet the AIC. 81 FR 43790, 43856. However, as discussed in section II.B.3.d of this final rule above, we are not finalizing our proposal under § 405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. Although we are finalizing separate calculations of the amount in controversy to address the situations in proposed § 405.1006(d)(3) through (7), we do not expect these provisions will have a meaningful effect on the number of appeals eligible for an ALJ hearing.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare a final regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

For purposes of the RFA, most providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. In addition, a number of MAOs and Part D plan sponsors (insurers) are small entities due to their nonprofit status; however, few if any meet the SBA size standard for a small insurance firm by having revenues of \$38.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. We have determined and we certify that this final rule would not

have a significant economic impact on a substantial number of small entities because as noted above, this final rule makes only minimal changes to the existing appeals procedures. Therefore, we did not prepare an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For final rules, this analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We have determined that this final rule would not have a significant effect on the operations of a substantial number of small rural hospitals. As noted above, this final rule makes only minimal changes to the existing appeals procedures and thus, would not have a significant impact on small entities or the operations of a substantial number of small rural hospitals. Therefore, we did not prepare an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$146 million. This final rule would not impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector in the amount of \$146 million in any one year, because as noted above, this final rule makes only minimal changes to the existing appeals procedures.

## VII. Federal Analysis

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes a proposed rule and subsequent final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule does not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate Federalism.

In accordance with the provisions of Executive Order 12866, this regulation

was reviewed by the Office of Management and Budget.

## List of Subjects

### 42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

### 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

### 42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

### 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

### 42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter IV as set forth below:

## PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

- 1. The authority citation for part 401 continues to read as follows:

**Authority:** Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

- 2. Section 401.109 is added to read as follows:

### § 401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential. In determining which decisions should be designated as precedential, the DAB Chair may take into consideration

decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the **Federal Register**.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

#### **PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

■ 3. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Section 405.902 is amended by adding the definitions of “Attorney Adjudicator”, “Council”, and “OMHA” in alphabetical order and removing the definition of “MAC”

The additions read as follows:

#### **§ 405.902 Definitions.**

*Attorney Adjudicator* means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided

for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

\* \* \* \* \*

*Council* stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

\* \* \* \* \*

*OMHA* stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

\* \* \* \* \*

■ 5. Section 405.904 is amended by revising paragraphs (a)(1) and (2) to read as follows:

#### **§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.**

(a) \* \* \*

(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Council to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the

reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

\* \* \* \* \*

#### **§ 405.906 [Amended]**

■ 6. Section 405.906(b) introductory text is amended by—

■ a. Removing from the paragraph heading the phrase “hearing and MAC” and adding “proceedings on a request for hearing, and Council review” in its place.

■ b. Removing the phrase “hearing, and MAC review” and adding “proceedings on a request for hearing, and Council review” in its place.

#### **§ 405.908 [Amended]**

■ 7. Section 405.908 is amended by removing the term “ALJ” and adding “OMHA” in its place and by removing the term “MAC” and adding “Council” in its place.

■ 8. Section 405.910 is amended by—

■ a. Revising paragraph (c)(5).

■ b. Adding paragraph (d)(3).

■ c. Revising paragraphs (f)(1) and (i)(2) and (3).

■ d. Revising paragraph (l).

■ e. Adding paragraph (m)(4).

The additions and revisions read as follows:

#### **§ 405.910 Appointed representatives.**

\* \* \* \* \*

(c) \* \* \*

(5) Identify the beneficiary's Medicare health insurance claim number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

\* \* \* \* \*

(d) \* \* \*

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to



the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

\* \* \* \* \*

(f) \* \* \*

(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

\* \* \* \* \*

(i) \* \* \*

(2) *Appeals.* When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

\* \* \* \* \*

(1) *Delegation of appointment by appointed representative.* (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (1)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (1)(1)(ii) of this section, unless the appointed representative and designee are attorneys in the same law firm or organization, in which case the notice described in paragraph (1)(1)(i) of this

section may be submitted even though the acceptance described in paragraph (1)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) \* \* \*  
(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

■ 9. Section 405.926 is amended by revising paragraphs (l) and (m) to read as follows:

**§ 405.926 Actions that are not initial determinations.**

\* \* \* \* \*

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

\* \* \* \* \*

**§ 405.956 [Amended]**

■ 10. Section 405.956(b)(8) is amended by removing the phrase "an ALJ hearing" and adding "the OMHA level" in its place.

■ 11. Section 405.968 is amended by revising paragraph (b)(1) to read as follows:

**§ 405.968 Conduct of a reconsideration.**

\* \* \* \* \*

(b) \* \* \*

(1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under § 401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

\* \* \* \* \*

■ 12. Section 405.970 is amended by revising the section heading and paragraphs (a) introductory text, (b), (c) introductory text, (e)(1), (e)(2)(i) and (ii) to read as follows:

**§ 405.970 Timeframe for making a reconsideration following a contractor redetermination.**

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC

mails, or otherwise transmits to the parties at their last known addresses, written notice of—

\* \* \* \* \*

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

\* \* \* \* \*

(e) \* \* \*

(1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) \* \* \*

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

■ 13. Section 405.972 is amended—  
 ■ a. By revising the section heading.  
 ■ b. In paragraph (b)(3) by removing the phrase "reconsideration of a contractor's dismissal" and adding "review of a contractor's dismissal" in its place.  
 ■ c. In paragraph (e) by adding the phrase "or attorney adjudicator" after the phrase "modified or reversed by an ALJ" and removing the phrase

“reconsideration of a contractor’s dismissal” and adding “review of a contractor’s dismissal” in its place.

The revision reads as follows:

**§ 405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor’s dismissal of a request for redetermination.**

\* \* \* \* \*

■ 14. Section 405.974 is amended by revising the section heading, the heading to paragraph (b), and paragraph (b)(3) to read as follows:

**§ 405.974 Reconsideration and review of a contractor’s dismissal of a request for redetermination.**

\* \* \* \* \*

(b) *Review of a contractor’s dismissal of a redetermination request.*

\* \* \* \* \*

(3) A QIC’s review of a contractor’s dismissal of a redetermination request is binding and not subject to further review.

■ 15. Section 405.976 is amended—

■ a. In paragraph (b)(5)(ii) by removing the phrase “at an ALJ level, or made part of the administrative record” and adding “at the OMHA level” in its place.

■ b. By revising paragraph (b)(7).

The revision reads as follows:

**§ 405.976 Notice of a reconsideration.**

\* \* \* \* \*

(b) \* \* \*

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

\* \* \* \* \*

**§ 405.978 [Amended]**

■ 16. Section 405.978(a) is amended by removing the phrase “An ALJ decision” and adding “An ALJ or attorney adjudicator decision” in its place.

■ 17. Section 405.980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(4) and (5), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

**§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.**

(a) \* \* \*

(1) \* \* \*

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

\* \* \* \* \*

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor’s, QIC’s, ALJ’s or attorney adjudicator’s, or Council’s decision on whether to reopen is binding and not subject to appeal.

\* \* \* \* \*

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.*

\* \* \* \* \*

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 405.986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision, at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986. If the Council’s decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by a party.*

\* \* \* \* \*

(2) A party to an ALJ or attorney adjudicator decision may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 405.986.

(3) A party to a Council review may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986.

**§ 405.982 [Amended]**

■ 18. Section 405.982(a) and (b) are amended by removing the phrase “ALJ, or the MAC” and adding the phrase “ALJ or attorney adjudicator, or the Council” in its place.

■ 19. Section 405.984 is amended—

■ a. In paragraph (c) by removing the phrase “in accordance with § 405.1000 through § 405.1064” and adding “in accordance with § 405.1000 through § 405.1063” in its place.

■ b. By revising paragraphs (d) and (e).  
The revisions read as follows:

**§ 405.984 Effect of a revised determination or decision.**

\* \* \* \* \*

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

\* \* \* \* \*

■ 20. Section 405.990 is amended—

■ a. In paragraph (a)(2) by removing the phrase “Medicare Appeals Council (MAC)” and adding the term “Council” in its place.

■ b. In paragraphs (b)(1) introductory text, (b)(1)(i)(B), (b)(4), and (d)(2)(ii) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ c. In paragraph (b)(1)(i)(A) by removing the phrase “the ALJ has” and adding “the ALJ or attorney adjudicator has” in its place.

■ d. In paragraph (b)(1)(ii) by removing the phrase “to the ALJ level” and adding “to OMHA for an ALJ hearing” in its place.

■ e. In paragraphs (c)(3), (4), and (5) by removing the term “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

■ f. By revising paragraph (d)(1).

■ g. In paragraph (d)(2)(i) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

■ h. In paragraph (d)(2)(ii) by removing the term “MAC’s” and adding “Council’s” in its place.

■ i. By revising paragraphs (i)(1) and (2).  
The revisions read as follows:

**§ 405.990 Expedited access to judicial review.**

\* \* \* \* \*

(d) \* \* \*

(1) *Method and place for filing request.* The requestor may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA, or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

\* \* \* \* \*

(j) \* \* \*

(1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

\* \* \* \* \*

■ 21. Section 405.1000 is revised to read as follows:

**§ 405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.**

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010, or join the hearing before an ALJ as a party under § 405.1012.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with § 405.1020(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a

decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

**§ 405.1002 [Amended]**

■ 22. Section 405.1002 is amended—

■ a. In paragraph (a) introductory text by removing the phrase “may request” and adding “has a right to” in its place.

■ b. In paragraph (a)(4) by removing the word “entity” and adding “office” in its place.

■ c. In paragraph (b)(1) by removing the phrase “to the ALJ level” and adding “for a hearing before an ALJ” in its place.

■ 23. Section 405.1004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

**§ 405.1004 Right to a review of QIC notice of dismissal.**

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

\* \* \* \* \*

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with § 405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with § 405.1052(b).

■ 24. Section 405.1006 is amended by—

■ a. Revising the section heading and paragraphs (d)(1) introductory text, (d)(1)(ii), and (d)(2).

■ b. Adding paragraphs (d)(3) through (6).

■ c. Revising paragraphs (e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory text, and (e)(2)(ii) and (iii).

The revisions and additions read as follows:

**§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.**

\* \* \* \* \*

(d) \* \* \*

(1) *In general.* The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—

\* \* \* \* \*

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Limitation on liability.* Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 of this chapter or if that liability was not limited under § 411.402 of this chapter, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

(3) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraph (d)(1) of this section, except that the

amount charged to the individual and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(4) *Overpayments.* Notwithstanding paragraph (d)(1) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter.

(5) *Coinsurance and deductible challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(6) *Fee schedule or contractor price challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) \* \* \*

(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

\* \* \* \* \*

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in

multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

\* \* \* \* \*

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

\* \* \* \* \*

■ 25. Section 405.1008 is revised to read as follows:

**§ 405.1008 Parties to the proceedings on a request for an ALJ hearing.**

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

■ 26. Section 405.1010 is revised to read as follows:

**§ 405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.**

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made—*(1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator, and the parties who were sent a copy of the notice of reconsideration.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (3) of this section, participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in paragraph (d)(3) of this section. However, the parties may provide testimony to rebut factual or policy statements made by a participant

and the ALJ may question the participant about its testimony.

(3) CMS or contractor position papers and written testimony are subject to the following:

(i) A position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled unless the ALJ grants additional time to submit the position paper or written testimony.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent within the same time frame specified in paragraph (c)(3)(i) of this section to—

(A) The parties who were sent a copy of the notice of reconsideration, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has been made a party to a hearing in accordance with § 405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with § 405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with § 405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the

precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with § 405.1012.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.

■ 27. Section 405.1012 is revised to read as follows:

**§ 405.1012 When CMS or its contractors may be a party to a hearing.**

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after the QIC receives the notice of hearing.

(2) Unless the request for hearing is filed by an unrepresented beneficiary, an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties identified in the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent within the same time frame specified in paragraph (c)(2)(i) of this section to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3), unless the ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation

as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

■ 28. Section 405.1014 is revised to read as follows:

**§ 405.1014 Request for an ALJ hearing or a review of a QIC dismissal.**

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant

wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the appellant will be provided with an opportunity to complete the request, and if an adjudication time frame applies, it does not begin until the request is complete. If the appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely, and any applicable time frame specified in § 405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the

materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or "cc" line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant, other than an unrepresented beneficiary, again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant's request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an

extension for good cause (See § 405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of a QIC dismissal with the office specified in the notice of reconsideration or dismissal.

(3) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of a QIC dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3).

(4) If a request for hearing is not timely filed, any applicable adjudication period in § 405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

■ 29. Section 405.1016 is revised to read as follows:

**§ 405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.**

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication

time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in § 405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with § 405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation.*—(1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council

by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with § 405.1102(a), and the appeal will be escalated to the Council for a review in accordance with § 405.1108; and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

■ 30. Section 405.1018 is revised to read as follows:

**§ 405.1018 Submitting evidence.**

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 405.1016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to



the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.*

(1) The requirements in paragraphs (a) and (b) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

(2) The requirements in paragraph (c) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

■ 31. Section 405.1020 is amended by—

■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).

■ b. Adding paragraphs (g)(3)(vii) and (viii).

■ c. Revising paragraphs (h), (i) paragraph heading, and (j)(1), (2), (4), and (5).

■ d. Adding paragraph (j).

The revisions and additions read as follows:

**§ 405.1020 Time and place for a hearing before an ALJ.**

\* \* \* \* \*

(b) *Determining how appearances are made—*(1) *Appearances by unrepresented beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an

individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record, the QIC that issued the reconsideration, and CMS or a contractor that elected to participate in the proceedings in accordance with § 405.1010(b) or that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the party or representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b). As provided in § 405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or

she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) \* \* \*

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

\* \* \* \* \*

(g) \* \* \*

(3) \* \* \*

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

\* \* \* \* \*

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with § 405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing

agrees to waive such adjudication time frame in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a).

■ 32. Section 405.1022 is revised to read as follows:

**§ 405.1022 Notice of a hearing before an ALJ.**

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 405.1032.

(2) The notice will inform the parties that they may designate a person to represent them during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other

party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with § 405.1020(e).

■ 33. Section 405.1024 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 405.1024 Objections to the issues.**

\* \* \* \* \*

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

■ 34. Section 405.1026 is revised to read as follows:

**§ 405.1026 Disqualification of the ALJ or attorney adjudicator.**

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator considers the party's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the party may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 405.1100 through § 405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with § 405.1016 is extended by 14 calendar days.

■ 35. Section 405.1028 is revised to read as follows:

**§ 405.1028 Review of evidence submitted by parties.**

(a) *New evidence—(1) Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to

obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

■ 36. Section 405.1030 is revised to read as follows:

**§ 405.1030 ALJ hearing procedures.**

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§ 405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with § 405.1028 for not producing the evidence earlier.

(d) *Effect of new evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 405.1016 is extended in accordance with § 405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 405.1022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice

of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 405.1022, except that the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date. ■ 37. Section 405.1032 is revised to read as follows:

**§ 405.1032 Issues before an ALJ or attorney adjudicator.**

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues—*(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the parties that were

or will be sent the notice of hearing about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations—(1) Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

■ 38. Section 405.1034 is revised to read as follows:

**§ 405.1034 Requesting information from the QIC.**

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. Prior to issuing a request for information to the QIC, OMHA will confirm whether an electronic copy of the redetermination or reconsideration is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS or its contractors” means the information is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

**§ 405.1036 [Amended]**

■ 39. Section 405.1036 is amended—

■ a. In paragraph (b)(1) by removing the phrase “send the ALJ” and adding “submit to OMHA” in its place.

■ b. By removing paragraph (d).

■ c. By redesignating paragraph (g) as new paragraph (d).

■ d. In paragraphs (f)(5)(i), (ii), (iii), (iv), (v), and (vi) by removing the term

“MAC” each time it appears and adding “Council” in its place.

■ e. In paragraphs (f)(5)(i) and (ii) by removing the term “MAC’s” and adding “Council’s” in its place.

■ f. In paragraph (f)(5)(i) by removing the phrase “specified in § 405.1102, § 405.1104, or § 405.1110” and adding “specified in § 405.1016(e) and (f), § 405.1102, or § 405.1110” in its place.

■ g. In paragraph (f)(5)(ii) by removing the phrase “discovery ruling” each time it appears and adding “subpoena ruling” in its place.

■ 40. Section 405.1037 is amended—

■ a. By revising paragraph (a)(1).

■ b. In paragraph (e)(1) by removing the phrase “specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110” and adding “specified in § 405.1016(e) and (f), § 405.1100, § 405.1102, or § 405.1110” in its place.

■ c. In paragraphs (e)(1), (e)(2) introductory text, (e)(2)(i), (ii), (iii), (iv), and (v) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ d. In paragraphs (e)(1) and (e)(2)(i) by removing the term “MAC’s” and adding “Council’s” in its place.

■ e. By revising paragraph (f).

The revisions read as follows:

**§ 405.1037 Discovery.**

(a) \* \* \*

(1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with § 405.1012.

\* \* \* \* \*

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

■ 41. Section 405.1038 is revised to read as follows:

**§ 405.1038 Deciding a case without a hearing before an ALJ.**

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with § 405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with § 405.1020(c) and who wish to appear.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

■ 42. Section 405.1040 is revised to read as follows:

**§ 405.1040 Prehearing and posthearing conferences.**

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing in accordance with § 405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the

conference notice if the parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

■ 43. Section 405.1042 is revised to read as follows:

**§ 405.1042 The administrative record.**

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the Council, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record from OMHA, including any

index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the requesting party obtains consent from the individual.

■ 44. Section 405.1044 is revised to read as follows:

**§ 405.1044 Consolidated proceedings.**

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an appellant to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022.

(b) *Consolidated or separate decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006 and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

■ 45. Section 405.1046 is revised to read as follows:

**§ 405.1046 Notice of an ALJ or attorney adjudicator decision.**

(a) *Decisions on requests for hearing—*

(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated

to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to § 405.1028, a discussion of the new evidence and the good cause determination that was made.

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924.

(b) *Decisions on requests for review of a QIC dismissal—(1) General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to all the parties at their last known address.

■ 46. Section 405.1048 is revised to read as follows:

**§ 405.1048 The effect of an ALJ's or attorney adjudicator's decision.**

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties unless—

(1) A party requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 405.980;

(3) The expedited access to judicial review process at § 405.990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in § 405.980.

**§ 405.1050 [Amended]**

■ 47. Section 405.1050 is amended—

■ a. In the section heading by removing the phrase “an ALJ” and adding “OMHA” in its place.

■ b. In the text of the section by removing the phrase “pending before an ALJ” and adding “pending before OMHA” in its place, and by removing the term “the ALJ” and adding “OMHA” in its place.

■ c. By removing the term “MAC” each time it appears and adding “Council” in its place wherever it appears.

■ 48. Section 405.1052 is revised to read as follows:

**§ 405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.**

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing, or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(2) The person or entity requesting a hearing has no right to it under § 405.1002.

(3) The party did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under § 405.1004.

(2) The party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to § 405.1014.

(4) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to all parties who were sent a copy of the request for hearing or review at their last known address. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 49. Section 405.1054 is revised to read as follows:



**§ 405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.**

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 405.1108(b), or vacated by the ALJ or attorney adjudicator under § 405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e).

■ 50. Section 405.1056 is added before the undesignated center heading “Applicability of Medicare Coverage Policies” to read as follows:

**§ 405.1056 Remands of requests for hearing and requests for review.**

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 405.1016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand—*(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may

jointly request a remand of the appeal to the entity that conducted the reconsideration. The request must include the reasons why the appeal should be remanded and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding a QIC’s dismissal of a request for reconsideration.* Consistent with § 405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC’s dismissal of a request for reconsideration was in error.

(e) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by a party or CMS or one of its contractors filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph are not available for and do not apply to remands that are issued under paragraph (d) of this section.

■ 51. Section 405.1058 is added before the undesignated center heading “Applicability of Medicare Coverage Policies” to read as follows:

**§ 405.1058 Effect of a remand.**

A remand of a request for hearing or request for review is binding unless

vacated by the Chief ALJ or a designee in accordance with § 405.1056(g).

**§ 405.1060 [Amended]**

■ 52. Section 405.1060 is amended—

■ a. In paragraph (a)(4) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place and removing the term “MAC” and adding “Council” in its place.

■ b. In paragraph (b) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place wherever it appears.

■ c. In paragraph (c) by removing the term “MAC” and adding “Council” in its place wherever it appears.

**§ 405.1062 [Amended]**

■ 53. Section 405.1062 is amended—

■ a. In the section heading and paragraphs (a) and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In paragraph (a) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place.

■ c. In the section heading and paragraph (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

■ d. In paragraph (c) by removing the phrase “An ALJ or MAC” and adding “An ALJ or attorney adjudicator or the Council” in its place.

■ 54. Section 405.1063 is revised to read as follows:

**§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.**

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social

Security Administration adjudicate matters under the jurisdiction of CMS.

**§ 405.1064 [Removed]**

- 55. Section 405.1064 is removed.
- 56. Section 405.1100 is revised to read as follows:

**§ 405.1100 Medicare Appeals Council review: General.**

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

- 57. Section 405.1102 is revised to read as follows:

**§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.**

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140), unless specifically excepted, the term "party", includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, "appellant," does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

**§ 405.1104 [Removed]**

- 58. Section 405.1104 is removed.
- 59. Section 405.1106 is revised to read as follows:

**§ 405.1106 Where a request for review or escalation may be filed.**

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of

the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

**§ 405.1108 [Amended]**

- 60. Section 405.1108 is amended—
- a. In the section heading and paragraphs (a), (b), (c), (d) introductory text, (d)(2), and (4) by removing the term "MAC" each time it appears and adding "Council" in its place.
- b. In paragraphs (a), (b), (c), (d)(1), and (5) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.
- c. In paragraphs (a) and (b) by removing the term "ALJ's" each time it appears and adding "ALJ's or attorney adjudicator's" in its place.
- d. In paragraph (b) by removing the first use of "dismissal" in the paragraph and adding "dismissal of a request for a hearing" in its place.
- e. In paragraph (d) introductory text by removing the term "ALJ level" and adding "OMHA level" in its place.
- f. In paragraph (d)(3) by removing the phrase "to an ALJ" and adding "to OMHA" in its place.
- 61. Section 405.1110 is revised to read as follows:

**§ 405.1110 Council reviews on its own motion.**

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or

dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and  
(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is issued. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's

or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

■ 62. Section 405.1112 is revised to read as follows:

**§ 405.1112 Content of request for review.**

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's

actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

**§ 405.1114 [Amended]**

- 63. Section 405.1114 is amended—
- a. In the introductory text and paragraphs (b) and (c)(1) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraph (c)(3) by removing the phrase “ALJ hearing” and adding “ALJ's or attorney adjudicator's action” in its place.

**§ 405.1116 [Amended]**

- 64. Section 405.1116 is amended by—
- a. Removing the term “MAC” each time it appears in the heading and text and adding “Council” in its place.
- b. Removing the term “MAC's” and adding “Council's” in its place.
- c. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

**§ 405.1118 [Amended]**

- 65. Section 405.1118 is amended by—
- a. Removing the term “MAC” each time it appears in the heading and text and adding “Council” in its place.
- b. Removing the phrase “ALJ hearing” and adding “ALJ's or attorney adjudicator's action” in its place.
- c. Removing the phrase “the exhibits list” and adding “any index of the administrative record” in its place.
- d. Removing the term “tape” and adding “audio recording” in its place.
- e. Removing the term “MAC's” and adding “Council's” in its place.

**§ 405.1120 [Amended]**

- 66. Section 405.1120 is amended in the heading and text by removing the term “MAC” each time it appears and adding “Council” in its place.

**§ 405.1122 [Amended]**

- 67. Section 405.1122 is amended—
- a. In the section heading and paragraphs (a) paragraph heading, (a)(1) and (2), (b) paragraph heading, (b)(1) and (2), (c)(1), (2), and (3) introductory text, (c)(3)(ii), (d)(1) and (3), (e)(1), (2), (3), and (4), and (f)(1), (2), and (3) by removing the term “MAC” each time it appears and adding “Council” in its place.

- b. In paragraphs (e)(5) and (6), and (f)(2) by removing the term “MAC’s” and adding “Council’s” in its place.
- c. In paragraph (a)(1) by removing the term “hearing decision” and adding “ALJ’s or attorney adjudicator’s decision” in its place.
- d. Amending paragraphs (a)(1) and (b)(1) by removing the term “ALJ level” and adding “OMHA level” in its place.
- e. In paragraphs (a)(1) and (2), (b)(1) and (2), (c)(2), (c)(3) introductory text, and (c)(3)(i) and (ii) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.
- f. In paragraph (a) heading and paragraph (a)(1) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.
- g. In paragraph (a)(2) by removing the term “hearing record” and adding “administrative record” in its place.

#### § 405.1124 [Amended]

- 68. Section 405.1124 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

#### § 405.1126 [Amended]

- 69. Section 405.1126 is amended—
- a. In the section heading and paragraphs (a), (b), (c), (d) paragraph heading, (d)(1) and (2), (e) paragraph heading, and (e)(1) and (2) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraph (b) by removing the term “MAC’s” and adding “Council’s” in its place.
- c. In paragraphs (a), (b), (c), (d) paragraph heading, and (e)(2) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.
- d. In paragraph (e)(2) by adding “if applicable” after the word “rehearing”.

#### § 405.1128 [Amended]

- 70. Section 405.1128 is amended—
- a. In the section heading and paragraphs (a), (b), and (c) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraph (a) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.
- c. In paragraph (b) by removing the term “ALJ hearing decision” and adding “ALJ’s or attorney adjudicator’s decision” in its place.

#### § 405.1130 [Amended]

- 71. Section 405.1130 is amended by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.

#### § 405.1132 [Amended]

- 72. Section 405.1132 is amended—

- a. In paragraphs (a) introductory text, (a)(2), and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraph (b) by removing the term “MAC’s” and adding “Council’s” in its place.
- c. In paragraphs (a) introductory text, (a)(1), and (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

#### § 405.1134 [Amended]

- 73. Section 405.1134 is amended—
- a. In paragraph (a) by removing the term “MAC’s” and adding “Council’s” in its place.
- b. In paragraphs (b)(3) and (c) by removing the term “MAC” and adding “Council” in its place.

#### § 405.1136 [Amended]

- 74. Section 405.1136 is amended—
- a. In paragraphs (a)(1) and (2), and (c)(3) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraph (a)(1) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.
- c. In paragraphs (a)(2) and (c)(2) by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.
- d. In paragraph (c)(3) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

#### § 405.1138 [Amended]

- 75. Section 405.1138 is amended by—
- a. Removing the term “MAC” each time it appears and adding “Council” in its place.
- b. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

#### § 405.1140 [Amended]

- 76. Section 405.1140 is amended—
- a. In the section heading and paragraphs (a)(1) through (3), (b)(1) through (3), (c) heading, (c)(1), (3), and (4), and (d) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In the section heading and paragraphs (a)(1) through (3), (b) heading, (b)(1) through (3), (c)(1) and (4), and (d) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.
- c. In paragraph (d) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.
- 77. Section 405.1204 is amended by revising paragraphs (c)(4)(iii) and (c)(5) to read as follows:

#### § 405.1204 Expedited reconsiderations.

\* \* \* \* \*

(c) \* \* \*  
(4) \* \* \*

(iii) Information about the beneficiary’s right to appeal the QIC’s reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006.

\* \* \* \* \*

## PART 422—MEDICARE ADVANTAGE PROGRAM

■ 78. The authority citation for part 422 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

#### § 422.561 [Amended]

- 79. Section 422.561 is amended in the definition of “Appeal” by removing the phrase “Medicare Appeals Council (MAC)” and adding “Medicare Appeals Council (Council)” in its place.
- 80. Section 422.562 is amended in paragraph (b)(4)(v) by removing the term “MAC” and adding “Council” in its place and by revising paragraphs (c)(1) and (d) to read as follows:

#### § 422.562 General provisions.

\* \* \* \* \*

(c) \* \* \*

(1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care the enrollee is not entitled to review of that issue by the MA organization.

\* \* \* \* \*

(d) *When other regulations apply.* (1) Unless this subpart provides otherwise and subject to paragraph (d)(2) of this section, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate.

(2) The following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

■ 81. Section 422.594 is amended by revising paragraph (b)(2) to read as follows:

**§ 422.594 Notice of reconsidered determination by the independent entity.**

\* \* \* \* \*

(b) \* \* \*

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600;

\* \* \* \* \*

■ 82. Section 422.602 is amended by revising paragraph (b) to read as follows:

**§ 422.602 Request for an ALJ hearing.**

\* \* \* \* \*

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020 of this chapter.

(2) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary.

\* \* \* \* \*

■ 83. Section 422.608 is revised to read as follows:

**§ 422.608 Medicare Appeals Council (Council) review.**

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, except as provided in § 422.562(d)(2).

**§ 422.612 [Amended]**

■ 84. Section 422.612 is amended—

■ a. In the paragraph (a) heading and paragraph (a) introductory text by removing the term “ALJ's” and adding “ALJ's or attorney adjudicator's” in its place.

■ b. In paragraph (a)(1) by removing the term “Board” and adding “Council” in its place.

■ c. In paragraph (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

**§ 422.616 [Amended]**

■ 85. Section 422.616 is amended in paragraph (a) by removing the terms “ALJ” and “MAC” and adding in their place “ALJ or attorney adjudicator” and “Council” respectively.

**§ 422.618 [Amended]**

■ 86. Section 422.618 is amended—

■ a. In paragraph (c)(1) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ b. In paragraph (c)(2) by removing the terms “Medicare Appeals Council”, “Medicare Appeals Council (the Board)”, and “Board” and adding “Council” in their place.

**§ 422.619 [Amended]**

■ 87. Section 422.619 is amended—

■ a. In paragraph (c)(1) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ b. In paragraph (c)(2) by removing the terms “Medicare Appeals Council”, “Medicare Appeals Council (the Board)”, and “Board” and adding “Council” in their place.

**§ 422.622 [Amended]**

■ 88. In § 422.622, paragraph (g)(2) is amended by removing the phrase “may appeal to an ALJ, the MAC, or a federal court” and adding “may appeal to OMHA for an ALJ hearing, the Council, or a Federal court” in its place.

**§ 422.626 [Amended]**

■ 89. In § 422.626, paragraph (g)(3) is amended by removing the phrase “to an

ALJ, the MAC, or a Federal court” and adding “to OMHA for an ALJ hearing, the Council, or a Federal court” in its place.

**PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

■ 90. The authority citation for part 423 continues to read as follows:

**Authority:** Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 91. Section 423.558 is amended by revising paragraph (b) to read as follows:

**§ 423.558 Scope.**

\* \* \* \* \*

(b) The requirements regarding reopenings, ALJ hearings and ALJ and attorney adjudicator decisions, Council review, and judicial review are set forth in subpart U of this chapter.

**§ 423.560 [Amended]**

■ 92. Section 423.560 is amended in the definition of “Appeal” by removing the term “Medicare Appeals Council (MAC)” and adding “Medicare Appeals Council (Council) in its place.

■ 93. Section 423.562 is amended by revising paragraphs (b)(4)(v) and (vi) to read as follows:

**§ 423.562 General provisions.**

\* \* \* \* \*

(b) \* \* \*

(4) \* \* \*

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in § 423.1974.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination, in whole or in part, the right to judicial review of the decision if the amount in controversy meets the requirements in § 423.1976.

\* \* \* \* \*

**Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review**

■ 94. The heading of subpart U is revised to read as set forth above.

■ 95. Section 423.1968 is revised to read as follows:

**§ 423.1968 Scope.**

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

■ 96. Section 423.1970 is amended by revising paragraphs (c)(1)(ii) and (iii) and (c)(2)(ii) and (iii) to read as follows:

§ 423.1970 Right to an ALJ hearing.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) \* \* \*

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

■ 97. Section 423.1972 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

§ 423.1972 Request for an ALJ hearing.

(a) How and where to file a request. The enrollee must file a written request for a hearing with the OMHA office specified in the IRE's reconsideration notice.

(b) When to file a request. (1) Except when an ALJ or attorney adjudicator extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 calendar

days of receipt of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020.

(2) For purposes of this section, the date of receipt of the reconsideration determination is presumed to be 5 calendar days after the date of the written reconsideration determination, unless there is evidence to the contrary.

(c) \* \* \*

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ or attorney adjudicator dismisses the request.

\* \* \* \* \*

■ 98. Section 423.1974 is revised to read as follows:

§ 423.1974 Council review.

An enrollee who is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal as provided in § 423.2102.

§ 423.1976 [Amended]

■ 99. Section 423.1976 is amended—

■ a. In the (a) paragraph heading and paragraph (a) introductory text by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ b. In paragraphs (a)(1) and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 423.1978 [Amended]

■ 100. In § 423.1978, paragraph (a) is amended by removing the phrase "ALJ or the MAC" and adding "ALJ or attorney adjudicator or the Council" in its place.

■ 101. Section 423.1980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(2) and (4), (d) heading, (d)(2) and (3), (e) heading, and (e)(2) and (3) to read as follows:

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) \* \* \*

(1) \* \* \*

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review,

no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

\* \* \* \* \*

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

\* \* \* \* \*

(d) Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.

\* \* \* \* \*

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.

\* \* \* \* \*

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

§ 423.1982 [Amended]

■ 102. Section 423.1982 is amended—

■ a. In paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term

“ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ b. In paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term “MAC” and adding “Council” in its place.

■ 103. Section 423.1984 is amended by revising paragraphs (d) and (e) to read as follows:

**§ 423.1984 Effect of a revised determination or decision.**

\* \* \* \* \*

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

\* \* \* \* \*

■ 104. Section 423.1990 is amended—

■ a. In paragraphs (a)(2), (b)(1) introductory text, (b)(1)(ii), and (b)(4) by removing the term “MAC” each time it appears and adding “Council” in its place

■ b. In paragraph (d)(2)(ii) by removing the term “MAC’s” and adding “Council’s” in its place.

■ c. In paragraph (b)(1)(i) by removing the phrase “final decision” and adding “decision” in its place and by removing the phrase “order of the ALJ” and adding “order of the ALJ or an attorney adjudicator” in its place.

■ d. In paragraph (b)(1)(ii) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ e. In paragraphs (c)(3), (4), and (5) by removing the term “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

■ f. By revising paragraph (d)(1).

■ g. In paragraph (d)(2)(i) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

■ h. By revising paragraph (h).

The revisions read as follows:

**§ 423.1990 Expedited access to judicial review.**

\* \* \* \* \*

(d) \* \* \*

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before

OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

\* \* \* \* \*

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

■ 105. Section 423.2000 is amended by revising the section heading and paragraphs (a), (b) through (e), and (g) to read as follows:

**§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.**

(a) If an enrollee is dissatisfied with an IRE’s reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in § 423.2010.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

\* \* \* \* \*

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

**§ 423.2002 [Amended]**

■ 106. Section 423.2002 is amended—

■ a. In paragraph (a) introductory text by removing the phrase “may request” and adding “has a right to” in its place.

■ b. In paragraph (c) by removing the phrase “The ALJ” and adding “OMHA” in its place.

■ c. In paragraph (e) by removing the word “entity” and adding “office” in its place.

■ 107. Section 423.2004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

**§ 423.2004 Right to a review of IRE notice of dismissal.**

(a) An enrollee has a right to have an IRE’s dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

(1) The enrollee files a written request for review within 60 calendar days after receipt of the notice of the IRE’s dismissal.

\* \* \* \* \*

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE’s dismissal.

(b) If the ALJ or attorney adjudicator determines that the IRE’s dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with § 423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE’s dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE’s dismissal in accordance with § 423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE’s dismissal in accordance with § 423.2052(b).

■ 108. Section 423.2008 is revised to read as follows:

**§ 423.2008 Parties to the proceedings on a request for an ALJ hearing.**

The enrollee (or the enrollee’s representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

■ 109. Section 423.2010 is revised to read as follows:

**§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.**

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to



participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made*—(1) *No notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request.* CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed.

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to

participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent within the same time frames specified in paragraph (d)(3)(i)(A) and (B) of this section to the enrollee.

(iii) If CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of its position paper or written testimony to the enrollee or fails to submit its position paper or written testimony within the time frames described in this section, the position paper or written testimony will not be considered in deciding the appeal.

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may

determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

(i) If no hearing is scheduled or the request to participate was made after the hearing occurred, the written notice of an invalid request to participate must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a non-expedited hearing is scheduled, the written notice of an invalid request to participate must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

■ 110. Section 423.2014 is revised to read as follows:

**§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.**

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(ii) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(2) The enrollee must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the enrollee will be provided with an opportunity to complete the request, and if an adjudication time frame applies it does not begin until the request is complete. If the enrollee fails to provide the information necessary to complete the request within the time frame provided, the enrollee's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(d) *When and where to file.* Consistent with § 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, the request is not treated as untimely, and any applicable time frame specified in § 423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) Consistent with § 423.1972(b), if the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee

may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or review of an IRE dismissal with the office specified in the notice of reconsideration or dismissal.

(4) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of an IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of an IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of an IRE dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3) of this chapter.

(5) If a request for hearing is not timely filed, any applicable adjudication period in § 423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(6) A determination granting a request to extend the filing deadline is not subject to further review.

■ 111. Section 423.2016 is revised to read as follows:

**§ 423.2016 Timeframes for deciding an appeal of an IRE reconsideration.**

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a)(1) of this section begins on the date that a timely filed request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(3) If the Council remands a case and the case was subject to an adjudication

time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal.* An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) *Grant of a request.* If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period

beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs (a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the matters at issue ordered by a court or tribunal of competent jurisdiction;

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

■ 112. Section 423.2018 is revised to read as follows:

**§ 423.2018 Submitting evidence.**

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the

coverage determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing pursuant to § 423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

■ 113. Section 423.2020 is amended by—

■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).

■ b. Adding paragraphs (g)(3)(vii) and (viii).

■ c. Revising paragraphs (h), (i) heading, and (i)(1), (2), (4), and (5).

■ d. Adding paragraph (j).

The revisions and additions read as follows:

**§ 423.2020 Time and place for a hearing before an ALJ.**

\* \* \* \* \*

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented enrollees.* The ALJ will direct that the appearance of an unrepresented enrollee who filed a

request for hearing be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented enrollee.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by represented enrollees.* The ALJ will direct that the appearance of an individual, other than an unrepresented enrollee who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by video-teleconferencing if he or she determines that video-teleconferencing is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b).

(1) As specified in § 423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

(e) \* \* \*

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause.

\* \* \* \* \*

(g) \* \* \*

(3) \* \* \*

(vii) The enrollee or enrollee's representative has a prior commitment that cannot be changed without significant expense.

(viii) The enrollee or enrollee's representative asserts he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee who filed the request for hearing objects to a telephone or video-

teleconferencing hearing, the enrollee or the enrollee's representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time and/or place he or she wants an in-person or video-teleconferencing hearing to be held.

\* \* \* \* \*

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with § 423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with § 423.2022(a)(2).

■ 114. Section 423.2022 is revised to read as follows:

**§ 423.2022 Notice of a hearing before an ALJ.**

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally

provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains—

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in the enrollee's favor and that were specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the enrollee fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the enrollee and in accordance with OMHA procedures.

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with § 423.2020(e).

■ 115. Section 423.2024 is amended in paragraph (a) by removing the phrase “The ALJ hearing office” and adding “OMHA” in its place and revising paragraph (c) to read as follows:

**§ 423.2024 Objections to the issues.**

\* \* \* \* \*

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

■ 116. Section 423.2026 is revised to read as follows:

**§ 423.2026 Disqualification of the ALJ or attorney adjudicator.**

(a) An ALJ or attorney adjudicator may not adjudicate an appeal if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee’s objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 423.2100 through § 423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

■ 117. Section 423.2030 is revised to read as follows:

**§ 423.2030 ALJ hearing procedures.**

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with § 423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee’s representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the enrollee or representative to stop such behavior, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with § 423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard appeal, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 423.2016 is extended in accordance with § 423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice

of the continued hearing must be sent in accordance with § 423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

■ 118. Section 423.2032 is revised to read as follows:

**§ 423.2032 Issues before an ALJ or attorney adjudicator.**

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee’s favor.

(b) *New issues—*(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS, the IRE, or the Part D plan sponsor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS, the IRE, or the Part D plan sponsor for the first time to the ALJ. The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue relating to a determination or appealed matter specified in the request for hearing, including a favorable portion of a determination or appealed

matter specified in the request for hearing, if its resolution could have a material impact on the appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to pending appeal if the coverage determination was adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with § 423.2014(e).

■ 119. Section 423.2034 is revised to read as follows:

**§ 423.2034 Requesting information from the IRE.**

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues can be provided only by CMS, the IRE, and/or the Part D plan sponsor. Prior to issuing a request for information to the IRE, OMHA will confirm whether an electronic copy of the missing redetermination or reconsideration is available in the official system of record,

and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS, the IRE, and/or the Part D plan sponsor” means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor Web site or information in an official CMS or HHS publication.

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

**§ 423.2036 [Amended]**

■ 120. Section 423.2036 is amended—

■ a. In paragraph (b)(1) introductory text by removing the phrase “send the ALJ” and adding “submit to OMHA” in its place.

■ b. In paragraph (b)(1)(ii) by removing the phrase “The ALJ hearing office” and adding “OMHA” in its place.

■ c. By removing paragraph (d).

■ d. By redesignating paragraph (g) as new paragraph (d).

■ e. In paragraphs (f)(2), (f)(3) introductory text, and (f)(3)(i), (ii), and (iii) by removing the term “MAC” and adding “Council” in its place.

■ f. In paragraph (f)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

■ 121. Section 423.2038 is revised to read as follows:

**§ 423.2038 Deciding a case without a hearing before an ALJ.**

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s)

prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.*

(1) The ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-conferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or payment may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

■ 122. Section 423.2040 is revised to read as follows:

**§ 423.2040 Prehearing and posthearing conferences.**

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice, if the enrollee consents to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of receiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

■ 123. Section 423.2042 is revised to read as follows:

**§ 423.2042 The administrative record.**

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conference and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including but not limited to duplicative evidence submitted by the enrollee.

(3) An enrollee may request and receive a copy of the record prior to or at the hearing, or, if a hearing is not

held, at any time before the notice of decision is issued.

(4) If a request for review is filed, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, an enrollee may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

(3) If the enrollee requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the enrollee is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the enrollee obtains consent from the individual.

■ 124. Section 423.2044 is revised to read as follows:

**§ 423.2044 Consolidated proceedings.**

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the

adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 423.2020 and 423.2022.

(b) *Consolidated decision and record.*

(1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the enrollee or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with § 423.1970 and the enrollees have all authorized disclosure of information to the other enrollees.

■ 125. Section 423.2046 is revised to read as follows:

**§ 423.2046 Notice of an ALJ or attorney adjudicator decision.**

(a) *Decisions on requests for hearing—*  
(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and



shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(2) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under § 423.566.

(b) *Decisions on requests for review of an IRE dismissal—(1) General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of an IRE dismissal, or the dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the IRE's dismissal. OMHA mails or otherwise transmits a copy of the decision to the enrollee.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to the enrollee at his or her last known address.

■ 126. Section 423.2048 is revised to read as follows:

**§ 423.2048 The effect of an ALJ's or attorney adjudicator's decision.**

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding unless—

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 423.1980;

(3) The expedited access to judicial review process at § 423.1990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in § 423.1980.

**§ 423.2050 [Amended]**

■ 127. Section 423.2050 is amended—

■ a. In the section heading by removing the phrase “an ALJ” and adding “OMHA” in its place.

■ b. In the text of the section by removing the phrase “pending before an ALJ” and adding “pending before OMHA” in its place, and by removing the term “the ALJ” and adding “OMHA” in its place.

■ c. In the section heading and the text of the section by removing the term

“MAC” each time it appears and adding “Council” in its place.

■ 128. Section 423.2052 is revised to read as follows:

**§ 423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.**

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(2) The person requesting a hearing has no right to it under § 423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The enrollee abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an enrollee has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(7) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under § 423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal

professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 129. Section 423.2054 is revised to read as follows:

**§ 423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.**

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 423.2108(b), or vacated by the ALJ or attorney adjudicator under § 423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under § 423.2052(e).

■ 130. Section 423.2056 is added to read as follows:

**§ 423.2056 Remands of requests for hearing and requests for review.**

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination in accordance with § 423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in § 423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period

that applies to the appeal in accordance with § 423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to the IRE, or its successor, to re-adjudicate the request for reconsideration.

(c) *Requested remand—(1) Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding an IRE's dismissal of a request for reconsideration.* Consistent with § 423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(e) *Consideration of change in condition.* The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination to be considered in the appeal.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand

procedures provided for in this paragraph are not available for and do not apply to remands that are issued under paragraph (d) of this section.

■ 131. Section 423.2058 is added to read as follows:

**§ 423.2058 Effect of a remand.**

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 423.2056(g).

**§ 423.2062 [Amended]**

■ 132. Section 423.2062 is amended—

■ a. In the section heading and paragraphs (a) and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In paragraph (a) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place.

■ c. In paragraph (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

■ 133. Section 423.2063 is revised to read as follows:

**§ 423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.**

(a) All laws and regulations pertaining to the Medicare program, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter are binding on all CMS components, and all HHS components that adjudicate matters under the jurisdiction of CMS.

■ 134. Section 423.2100 is revised to read as follows:

**§ 423.2100 Medicare Appeals Council review: general.**

(a) Consistent with § 423.1974, the enrollee may request that the Council review an ALJ’s or attorney adjudicator’s decision or dismissal.

(b) When the Council reviews an ALJ’s or attorney adjudicator’s written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar

day period beginning on the date the request for review is received (by the entity specified in the ALJ’s or attorney adjudicator’s written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee’s health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ’s or attorney adjudicator’s written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

■ 135. Section 423.2102 is revised to read as follows:

**§ 423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.**

(a)(1) An enrollee may request Council review of a decision or dismissal issued by an ALJ or attorney adjudicator if the enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ’s or attorney adjudicator’s written decision or dismissal.

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ’s or attorney adjudicator’s written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee’s request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ’s or attorney adjudicator’s written decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ’s or attorney adjudicator’s action.

(b) An enrollee requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ’s or attorney adjudicator’s remand to an IRE, or an ALJ’s or attorney adjudicator’s affirmation of an IRE’s dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

**§ 423.2106 [Amended]**

■ 136. Section 423.2106 is amended by—

■ a. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ b. Removing the term “ALJ’s” each time it appears and adding “ALJ’s or attorney adjudicator’s” in its place.

■ c. Removing the term “MAC” each time it appears and adding “Council” in its place.

■ d. Removing the term “MAC’s” and adding “Council’s” in its place.

**§ 423.2108 [Amended]**

■ 137. Section 423.2108 is amended by—

■ a. In paragraphs (a) through (c) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ b. In paragraphs (a) and (d)(2)(iii) by removing the term “ALJ’s” each time it appears and adding “ALJ’s or attorney adjudicator’s” in its place.

■ c. In the section heading and paragraphs (a) through (c), (d)(1), (d)(2) introductory text, (d)(3) introductory text, and (d)(3)(ii) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ d. In paragraph (a) by removing the term “MAC’s” and adding “Council’s” in its place.

■ e. In the heading and text of paragraph (b) by removing the phrase “ALJ’s dismissal” and adding “ALJ’s or attorney adjudicator’s dismissal of a request for a hearing” in its place.

■ 138. Section 423.2110 is revised to read as follows:

**§ 423.2110 Council reviews on its own motion.**

(a) *General rule.* The Council may decide on its own motion to review a

decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days after the date of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review—(1) Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or*

*request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

#### § 423.2112 [Amended]

■ 139. Section 423.2112 is amended—

■ a. In paragraphs (a)(1), (b), and (c) by removing the term “ALJ's” and adding “ALJ's or attorney adjudicator's” in its place.

■ b. In paragraph (b) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ c. In paragraphs (a)(1) and (3) and (c) by removing the term “MAC” and adding “Council” in its place.

#### § 423.2114 [Amended]

■ 140. Section 423.2114 is amended in the introductory text and paragraph (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

#### § 423.2116 [Amended]

■ 141. Section 423.2116 is amended by—

■ a. Removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. Removing the term “MAC's” and adding “Council's” in its place.

■ c. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

#### § 423.2118 [Amended]

■ 142. Section 423.2118 is amended by—

■ a. Removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. Removing the term “MAC's” and adding “Council's” in its place.

■ c. Removing the phrase “ALJ hearing” and adding “ALJ's or attorney adjudicator's action” in its place.

■ d. Removing the phrase “the exhibits list” and adding “any index of the administrative record” in its place.

■ e. Removing the term “CD” and adding “audio recording” in its place.

#### § 423.2120 [Amended]

■ 143. Section 423.2120 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

#### § 423.2122 [Amended]

■ 144. Section 423.2122 is amended—

■ a. In the section heading and paragraphs (a) paragraph heading, (a)(1) through (3), (b) introductory text, (b)(1) and (2), and (c)(1) through (4) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In paragraphs (a) heading and (a)(1) by removing the term “ALJ's” and adding “ALJ's or attorney adjudicator's” in its place.

■ c. In paragraph (a)(1) by removing the term “ALJ level” and adding “OMHA level” in its place.

■ d. In paragraph (a)(1) by removing the term “hearing decision” and adding “ALJ's or attorney adjudicator's decision” in its place.

■ e. In paragraphs (a)(1) and (2) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ f. In paragraph (a)(2) by removing the term “hearing record” and adding “administrative record” in its place.

■ g. In paragraph (c)(3) by removing the term “MAC's” and adding “Council's” in its place.

#### § 423.2124 [Amended]

■ 145. Section 423.2124 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

#### § 423.2126 [Amended]

■ 146. Section 423.2126 is amended—

■ a. Amending the section heading and paragraphs (a) heading, (a)(1) through (3), (a)(4) heading, (a)(4)(i) and (ii), (a)(5) heading, (a)(5)(i) and (ii), and (b) by

removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In paragraphs (a) heading, (a)(1) through (3), (a)(4) heading, and (a)(5)(ii) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

■ c. In paragraph (a)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

■ d. In paragraph (a)(5)(ii) by adding “if applicable” after the word “rehearing”.

#### § 423.2128 [Amended]

■ 147. Section 423.2128 is amended—

■ a. In the section heading and paragraphs (a), (b), and (c) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In paragraph (a) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

■ c. In paragraph (b) by removing the phrase “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

#### § 423.2130 [Amended]

■ 148. Section 423.2130 is amended by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.

#### § 423.2134 [Amended]

■ 149. Section 423.2134 is amended in paragraphs (b)(3) and (c) by removing the term “MAC” and adding “Council” in its place.

#### § 423.2136 [Amended]

■ 150. Section 423.2136 is amended—

■ a. In paragraphs (a) and (c)(3) by removing the term “MAC” and adding “Council” in its place.

■ b. In paragraph (c)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

■ c. In paragraph (c)(3) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

#### § 423.2138 [Amended]

■ 151. Section 423.2138 is amended by—

■ a. Removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

#### § 423.2140 [Amended]

■ 152. Section 423.2140 is amended—

■ a. In the section heading and paragraphs (a)(1) through (3), (b)(1), (b)(2) introductory text, (b)(2)(ii), (b)(3) and (4), (c) heading, (c)(1), (3), and (4), and (d) by removing the term “MAC” each time it appears and adding “Council” in its place.

■ b. In the section heading and paragraphs (a)(1) through (3), (b) heading, (b)(1), (b)(2) introductory text, (b)(2)(i), (b)(3) and (4), (c)(1) and (4), and (d) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

■ c. In paragraph (d) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

#### PART 478—RECONSIDERATIONS AND APPEALS

■ 153. The authority citation for part 478 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

#### § 478.40 [Amended]

■ 154. In § 478.14, paragraph (c)(2) is amended by removing the phrase “part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B” and adding “part 405, subpart I of this chapter for determinations under Medicare Part A and Part B” in its place.

■ 155. Section 478.40 is amended by revising paragraphs (a) and (c) to read as follows:

#### § 478.40 Beneficiary’s right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least \$200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may request a hearing by an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).

\* \* \* \* \*

(c) *Governing provisions.* (1) The provisions of subpart I of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart or specified in paragraph (c)(2) of this section. Except as provided in paragraph (c)(2) of this section, references in subpart I to initial determinations made by a Medicare contractor and reconsiderations made by a QIC should be read to mean initial determinations and reconsidered determinations made by a QIO.

(2) The following part 405 regulations, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ’s or attorney adjudicator’s decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

■ 156. Section 478.42 is revised to read as follows:

#### § 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 478.40 must submit a written request to the OMHA office identified in the notice of the QIO reconsidered determination.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 478.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be 5 calendar days after the date on the notice, unless there is evidence to the contrary.

(3) A request is considered filed on the date it is received by OMHA.

■ 157. Section 478.44 is revised to read as follows:

#### § 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter. When two or more appellants submit a request for hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter.

(b) If the ALJ or attorney adjudicator determines that the amount in controversy is less than \$200, the ALJ,

without holding a hearing, or attorney adjudicator notifies the parties that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least \$200.

(c) At the end of the 15-day period, if an ALJ determines that the amount in controversy is less than \$200, the ALJ, without holding a hearing dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

■ 158. Section 478.46 is revised to read as follows:

**§ 478.46 Medicare Appeals Council and judicial review.**

(a) The circumstances under which the Medicare Appeals Council (Council) will review an ALJ's or attorney adjudicator's decision or dismissal are the same as those set forth at

§§ 405.1102 ("Request for Council review when ALJ or attorney adjudicator issues decision or dismissal") and 405.1110 ("Council reviews on its own motion") of this chapter.

(b) If \$2,000 or more is in controversy, a party may obtain judicial review of a Council decision, or an ALJ's or attorney adjudicator's decision if a request for review by the Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Council decision or denial.

■ 159. Section 478.48 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

**§ 478.48 Reopening and revision of a reconsidered determination or a decision.**

\* \* \* \* \*

(b) *ALJ or attorney adjudicator and Council Reopening—Applicable procedures.* The ALJ or attorney

adjudicator, or the Council, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.980 of this chapter, which concerns reopenings and revised decisions under subpart I of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or attorney adjudicator, or the Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

Approved: December 22, 2016.

**Sylvia Burwell,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2016-32058 Filed 1-13-17; 8:45 am]

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Part III

## Environmental Protection Agency

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40 CFR Part 61

Revisions to National Emission Standards for Radon Emissions From  
Operating Mill Tailings; Final Rule



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 61

[EPA-HQ-OAR-2008-0218; FRL-9957-54-OAR]

RIN 2060-AP26

### Revisions to National Emission Standards for Radon Emissions From Operating Mill Tailings

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to revise certain portions of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Radon Emissions from Operating Mill Tailings. The revisions for this final action are based on the EPA's determination as to what constitutes generally available control technology or management practices (GACT) for this area source category. We are also adding new definitions to the NESHAP, revising existing definitions and clarifying that the NESHAP also applies to uranium recovery facilities that extract uranium through the in-situ leach method and the heap leach method.

**DATES:** This rule is effective on March 20, 2017.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2008-0218. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Dan Schultheisz, Office of Radiation and Indoor Air, Radiation Protection Division, Mail code 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202-343-9290; fax number: 202-343-2304; email address: [schultheisz.daniel@epa.gov](mailto:schultheisz.daniel@epa.gov). You may also access the EPA Web site to find information related to this rulemaking at <https://www.epa.gov/radiation/>.

### SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

Preamble Acronyms and Abbreviations. We use the following acronyms and abbreviations in this document:

AEA—Atomic Energy Act  
 ALARA—As low as reasonably achievable  
 BID—Background information document  
 CAA—Clean Air Act  
 CAAA—Clean Air Act Amendments of 1990  
 CCAT—Colorado Citizens Against Toxic Waste  
 CFR—Code of Federal Regulations  
 Ci—Curie, a unit of radioactivity equal to the amount of a radioactive isotope that decays at the rate of  $3.7 \times 10^{10}$  disintegrations per second  
 DOE—U.S. Department of Energy  
 EIA—Economic impact analysis  
 EO—Executive Order  
 EPA—U.S. Environmental Protection Agency  
 FR—Federal Register  
 GACT—Generally Available Control Technology  
 HAP—Hazardous Air Pollutant  
 ISL—In-situ leach uranium recovery, also known as in-situ recovery (ISR)  
 mrem—millirem,  $1 \times 10^{-3}$  rem—a unit of radiation exposure  
 MACT—Maximum Achievable Control Technology  
 MOU—Memorandum of Understanding  
 NESHAP—National Emission Standard for Hazardous Air Pollutants  
 NRC—U.S. Nuclear Regulatory Commission  
 NTAA—National Tribal Air Association  
 OMB—Office of Management and Budget  
 pCi—picocurie,  $1 \times 10^{-12}$  curie  
 Ra-226—Radium-226  
 Rn-222—Radon-222  
 Radon flux—A term applied to the amount of radon crossing a unit area per unit time, as in picocuries per square centimeter per second (pCi/m<sup>2</sup>/sec)  
 RCRA—Resource Conservation and Recovery Act  
 Subpart W—National Emission Standards for Radon Emissions from Operating Mill Tailings at 40 CFR 61.250–61.256  
 SWIPR—Subpart W Impoundment Photographic Reporting  
 tpy—tons per year  
 U<sub>3</sub>O<sub>8</sub>—uranium oxide, also known as “yellowcake”  
 UMTRCA—Uranium Mill Tailings Radiation Control Act of 1978  
 U.S.C.—United States Code

**Background Information.** In this action we are finalizing changes to the NESHAP for Radon Emissions from Operating Mill Tailings. These changes were proposed on May 2, 2014 (79 FR 25388) as part of a review of pre-1990 NESHAPs pursuant to Clean Air Act Section 112(q)(1). After review of the public comments we have made some changes to the rule since the proposal, and these will be discussed later in this document. We summarize some of the more significant comments received regarding the proposed rule and provide

our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is provided in the “Summary and Response to Public Comments” document, which is available in Docket ID No. EPA-HQ-OAR-2008-0218. The “track changes” version of the regulatory language that incorporates the changes in this final action resulting from review by the Office of Management and Budget (OMB) is also available in the docket for this rulemaking.

**Outline.** The information in this preamble is organized as follows:

- I. General Information
  - A. Executive Summary
    1. Introduction
    2. Provisions of the 1989 Rule
    3. Provisions of the Final Rule
    4. Key Changes to the Proposal
    5. Economic Impacts
    6. Public Engagement
  - B. Does this action apply to me?
  - C. Where can I get a copy of this document and other related information?
  - D. Judicial Review and Administrative Reconsideration
- II. Background
  - A. What is the Agency's legal authority for taking this action?
  - B. What source category is affected by the final rule?
  - C. How does Subpart W regulate HAP emissions from the source category?
  - D. What changes to Subpart W did we propose?
  - E. Comments on the Proposed Rule
- III. What Final Amendments Are We Issuing With This Action?
  - A. Application of Generally Available Control Technologies (GACT) to Uranium Recovery Facilities
  - B. Definitions, References and Conforming Editorial Revisions
  - C. What are the recordkeeping, notification and reporting requirements?
- IV. What is the rationale for our final decisions and amendments to Subpart W?
  - A. Legal Authorities and GACT
    1. What is the legal authority for GACT standards and management practices in the final rule?
    2. What key comments did we receive on our legal authorities and the GACT approach?
  - B. Retaining the Radon Flux Requirement for Impoundments in Existence on December 15, 1989
    1. How did we address the radon flux standard in the proposed and final rules?
    2. What did our updated risk assessment tell us?
    3. What key comments did we receive on the radon flux standard?
  - C. GACT for Conventional Impoundments Constructed After December 15, 1989
    1. How did we address conventional impoundments constructed after December 15, 1989 in the proposed and final rules?

2. What key comments did we receive on conventional impoundments constructed after December 15, 1989?
- D. GACT for Heap Leach Piles
  1. How did we address heap leach piles in the proposed and final rules?
  2. What key comments did we receive on heap leach piles?
- E. GACT for Non-Conventional Impoundments
  1. How did we address non-conventional impoundments in the proposed and final rules?
  2. What key comments did we receive on non-conventional impoundments?
- F. Definitions, References and Conforming Editorial Revisions
  1. How did we address definitions, references and conforming editorial revisions in the proposed and final rules?
  2. What key comments did we receive on definitions, references and conforming editorial revisions?
- V. Summary of Environmental, Cost and Economic Impacts
  - A. What are the air impacts?
  - B. What are the cost and economic impacts?
  - C. What are the non-air environmental impacts?
- VI. Statutory and Executive Orders Review
  - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  - B. Paperwork Reduction Act (PRA)
  - C. Regulatory Flexibility Act (RFA)
  - D. Unfunded Mandates Reform Act (UMRA)
  - E. Executive Order 13132: Federalism
  - F. Executive Order 13175: Consultation
  - G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
  - I. National Technology Transfer and Advancement Act (NTTAA)
  - J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
  - K. Congressional Review Act (CRA)

## I. General Information

### A. Executive Summary

#### 1. Introduction

This final rule amends requirements promulgated in 1989 under the Clean Air Act to control emissions of radon-222 from operating structures used to manage uranium byproduct material or tailings<sup>1</sup> at uranium recovery facilities.

<sup>1</sup> The EPA first defined the term “uranium byproduct material or tailings” in 1986 (51 FR 34066). The 1986 and 1989 rulemakings were primarily concerned with, but not limited to, conventional mill tailings as the most significant source of radon. We used the term “tailings” throughout those rulemakings for simplicity, reflecting that rulemaking emphasis. We

The rule does not apply to disposal of uranium byproduct material or tailings. The rule retains monitoring requirements for certain uranium byproduct material or tailings impoundments in existence on or before December 15, 1989 and establishes generally available control technology or management practices (GACT) for other impoundments and heap leach piles. This final rule completes the EPA’s obligation under the requirements of CAA section 112(q)(1) to “review, and if appropriate, revise” 40 CFR part 61, subpart W (hereafter Subpart W).

Uranium recovery and processing currently occurs by one of three methods: (1) Conventional milling; (2) in-situ leach (ISL); and (3) heap leach. A conventional uranium mill is a chemical plant that extracts uranium from ore that has typically been obtained from an underground or open-pit mine. The ore is crushed and the uranium leached using chemical solutions, concentrated into uranium oxide (U<sub>3</sub>O<sub>8</sub> or “yellowcake”), and transported to a uranium conversion facility to begin the processing into fuel for nuclear reactors. Solid and liquid wastes produced during this process are called uranium byproduct material or tailings. Uranium byproduct material or tailings contains residual uranium, radium and heavy metals. Radon-222 is generated by the decay of radium-226. As defined in this final rule, conventional impoundments are used to manage the mostly solid wastes from processing. Non-conventional impoundments, also known as evaporation or holding ponds, are used to manage process liquids and effluents. Non-conventional impoundments may accumulate sediments at the bottom as solids contained in the liquids settle out. Conventional impoundments are permanent structures that require long-term stewardship. Non-conventional impoundments are typically removed at facility closure and often placed into conventional impoundments for disposal. Non-conventional impoundments are sometimes also designed to be used as conventional impoundments as needed.

ISL is often used when a uranium ore body is in a formation through which ground water flows. A liquid solution containing chemicals can be injected

understand that this has contributed to the impression among some stakeholders that Subpart W cannot apply to materials other than the mostly solid wastes resulting from conventional milling that are managed, and ultimately disposed, in permanent impoundments. We are reiterating in this action that the term “uranium byproduct material or tailings” more broadly defines the materials that are subject to Subpart W.

into the formation to mobilize the uranium into solution, which is then recovered and processed. Process liquids and effluents from ISL are managed in non-conventional impoundments. ISL is now the predominant form of uranium recovery in the United States.

Heap leaching is a method of processing that is expected to be used for low-grade ore or in other situations where it is economically favorable. During heap leaching a pile of ore is sprayed with a chemical solution and uranium leaches into solution. The uranium solution is collected at the bottom of the pile and further processed. At the end of processing, the heap leach pile may be closed in place (typically by being covered), or removed and placed in a conventional impoundment. Process liquids and effluents are managed in non-conventional impoundments. At the time of this rulemaking, there are no heap leach facilities in the United States, although one such facility is planned.

There is currently one operating conventional mill in the United States, the White Mesa Mill in Utah. Two other conventional mills remain on standby, the Shootaring Canyon Mill in Utah and the Sweetwater Mill in Wyoming. There are six operating ISL facilities: Crow Butte in Nebraska; Smith Ranch, Lost Creek, Nichols Ranch, Willow Creek (which includes the Irigary and Christensen Ranch wellfields) and Ross CPP, all in Wyoming. Four other ISL facilities have operated and are now in standby. They are Alta Mesa, Kingsville Dome,<sup>2</sup> Rosita and Hobson/La Palangana, all located in Texas. These facilities are subject to the requirements of Subpart W. There are no heap leach facilities operating or on standby. Future heap leach facilities, as well as conventional mills and ISL facilities that have been or are being licensed, will be subject to Subpart W when they begin operating.

Subpart W was initially promulgated in 1986 and amended pursuant to a voluntary remand in 1989. For CAA section 112 standards that were in effect before November 15, 1990, CAA section 112(q)(1) requires the EPA to review, and, if appropriate, revise such standards to comply with the requirements of subsection (d). As a result of this review, we are promulgating this final rule pursuant to

<sup>2</sup> Operating permits at the Kingsville Dome facility have lapsed and may not be renewed; however, because there are still uranium resources that could be exploited, Kingsville Dome is considered to be on standby for purposes of this discussion.

CAA sections 112(q) and 112(d) and setting standards that comply with the requirements of CAA section 112(d)(5). CAA section 112(d)(5) addresses standards for area sources and provides that section 112(d) standards for area sources may provide for the use of GACT by the affected area sources.

Subpart W regulates facilities and materials that are also regulated under the authority of the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA). UMTRCA directed the EPA to establish standards of general application to protect public health, safety and the environment from hazards associated with wastes from extraction or concentration of uranium or thorium. The Nuclear Regulatory Commission (NRC) implements and enforces the EPA's standards through its licensing and regulatory program. By establishing requirements to control radon emissions from uranium byproduct material or tailings during the facility's operational period, Subpart W supports and works in harmony with the NRC's UMTRCA-based provisions that limit radon concentrations at the site boundary.

## 2. Provisions of the 1989 Rule

When promulgated in 1989, Subpart W established monitoring requirements and work practices as methods to control radon emissions from impoundments used to manage uranium byproduct material or tailings (51 FR 51654, December 15, 1989). Existing impoundments (those operating as of December 15, 1989) were required to comply with a radon flux standard of 20 pCi/m<sup>2</sup>-sec, monitored using Method 115. New impoundments built after December 15, 1989 were required to be operated in accordance with the provisions of 40 CFR 192.32(a) and be designed to meet one of two work practices:

- Phased disposal in impoundments no larger than 40 acres in area, with no more than two such impoundments operating at any one time; or
- Continuous disposal of tailings such that tailings are dewatered and immediately disposed with no more than 10 acres of tailings exposed at any one time.

All impoundments were required to be operated to comply with the requirements of 40 CFR 192.32(a),<sup>3</sup>

notwithstanding the exemption in § 192.32(a)(1) for impoundments constructed prior to the promulgation of 40 CFR part 192. This provision was incorporated to ensure that older impoundments were equipped with liners capable of retaining liquids within the impoundment and monitoring systems capable of detecting leakages. Leaks could allow the contents of the impoundment to dry out and increase radon emissions. As originally promulgated in 1986, Subpart W envisioned that older impoundments would not be in use beyond December 31, 1992 unless granted an exemption or extension. Such impoundments were not required to comply with the provisions of 40 CFR 192.32(a). The 1989 rulemaking eliminated the prohibition on using existing impoundments beyond December 31, 1992 and required older impoundments to comply with the requirements at 40 CFR 192.32(a) (51 FR 34066, September 24, 1986 and 54 FR 51680, December 15, 1989).

## 3. Provisions of the Final Rule

This final rule defines and establishes GACT-based standards for conventional and non-conventional impoundments and heap leach piles; in doing so, the final rule clarifies the applicability of the 1989 rule to these different types of units and distinguishes among them. The final rule retains the radon flux standard and monitoring requirements for conventional impoundments in existence on December 15, 1989, and retains the provision that extended the construction requirements in 40 CFR 192.32(a)(1) to these conventional impoundments. The final rule also formalizes the 1989 management practices as GACT-based standards for conventional impoundments constructed after December 15, 1989, with limited changes to the 1989 standard—the final rule focuses the cross-reference regarding the impoundment construction requirements to 40 CFR 192.32(a)(1), instead of a more broad reference to 40 CFR 192.32(a) and removes the phrase “as determined by the Nuclear Regulatory Commission.” In addition, the final rule establishes GACT-based standards for non-conventional

impoundments and heap leach piles, as follows:

- Non-conventional impoundments must maintain solid materials in a saturated condition, with no solid materials visible above the level of liquid in the impoundment;
- Heap leach piles that have completed their operational life but not yet entered closure are limited to no more than two such piles with an area no greater than 40 acres each; and
- Conformance to the construction requirements in 40 CFR 192.32(a)(1).

The final rule changes some existing definitions and adds several new definitions. The amended definition of “operation” is finalized as proposed. The definitions of “continuous disposal,” “dewatered,” “existing impoundment,” and “phased disposal” are amended to conform to the amended definition of “operation.” New definitions of “standby,” “conventional impoundment,” “non-conventional impoundment,” “heap leach pile,” “heap leach pile operational life,” and “uranium recovery facility” are also being finalized as proposed. New definitions of “final closure” and “reclamation plan” are added to the final rule to clarify when Subpart W no longer applies to an impoundment or heap leach pile.

## 4. Key Changes to the Proposal

The proposed rule contained several provisions that are modified in the final rule in response to public comments. We proposed to eliminate the radon flux standard and monitoring requirement for impoundments in existence on December 15, 1989. We believed this was appropriate based on information that indicated that the remaining impoundments in this category could comply with the GACT-based management practices. Information received through public comments demonstrated that the assumptions that supported our proposal were not correct and also that the pre-1989 unit that was expected to close (Cell 3 at the White Mesa Mill) remains open. Therefore, the final rule retains the radon flux standard and monitoring requirement for conventional impoundments in existence on December 15, 1989.

We proposed that non-conventional impoundments maintain one meter of liquid above any solid materials in the impoundment. Our analyses indicate that liquids effectively attenuate radon emissions, and that one meter of liquid would reduce the radon emissions by greater than 99%, to a level nearly indistinguishable from background. Based on public comment regarding feasibility and cost associated with the

<sup>3</sup> 40 CFR 192.32(a) includes six elements, which apply during processing and prior to the end of the closure period: (1) Construction of impoundments in conformance with the requirements of 40 CFR 264.221; (2) conformance to the groundwater protection standards in 40 CFR 264.92 and related sections; (3) placement of a permanent radon barrier on nonoperational impoundments; (4)

demonstration that the permanent radon barrier limits radon releases to no greater than 20 pCi/m<sup>2</sup>-sec; (5) conformance to the requirements of 40 CFR part 190 and 40 CFR part 440; and (6) maintenance by NRC of public doses from radon emissions as far below the Federal Radiation Protection Guidance as practicable. Only § 192.32(a)(1) is directly relevant to the goals of Subpart W, which in turn facilitate NRC in achieving § 192.32(a)(6).

water demand to maintain the liquid level in the impoundment, the final rule requires only that solid materials remain saturated. Saturation will effectively reduce radon emissions by approximately 95% compared to dry uranium byproduct material or tailing. The water demand to maintain saturation should also be considerably reduced compared to the proposal.

We proposed that heap leach piles be regulated under Subpart W from the time they begin processing (*i.e.*, at the time the leaching solution is first applied), because uranium byproduct material or tailings begins to be generated at that time. We proposed they be limited in size (40 acres) and number (no more than two operating at any one time), and maintain a 30% moisture content to reduce radon emissions. Based on public comment, the final rule provides that heap leach piles become subject to Subpart W once they have finished their operational life, when their sole purpose is to manage uranium byproduct material or tailings.

As commenters pointed out, this is consistent with the approach we have taken for conventional mills, where waste material that has been separated from the recovered uranium has not been regulated under Subpart W until it leaves the processing unit and is deposited in an impoundment. Further, Subpart W will only apply to post-processing heap leach piles until they enter the closure process. The final rule retains the proposed area and number limitations on piles that are between processing and closure.

5. Economic Impacts

This final rule will have limited economic impact. No new requirements are placed on conventional impoundments. Further, impacts associated with non-conventional impoundments and heap leach piles will be less than those estimated for the proposed rule. Operators of non-conventional impoundments and heap leach piles will not incur additional cost related to liners, which are required by other regulations. Operators of non-

conventional impoundments will be required to maintain liquids in the impoundment such that no solids are visible above the liquid level. In addition, operators of heap leach facilities can reduce the period of time they are subject to Subpart W and thus reduce compliance costs by expeditiously beginning the closure process after the operational life of the pile has ended, and we encourage timely closure in all cases.

Table 1 presents a summary of the unit cost (per pound of U<sub>3</sub>O<sub>8</sub>) for implementing each GACT-based standard at each of the three types of uranium recovery facilities. In addition to presenting the GACT costs individually, Table 1 presents the total unit cost to implement all relevant GACT-based standards at each type of facility. Table 1 shows that a conventional mill will have both conventional and non-conventional impoundments, and be required to maintain saturation in the non-conventional impoundments.

TABLE 1—FINAL GACT-BASED STANDARDS COSTS PER POUND OF U<sub>3</sub>O<sub>8</sub>

	Unit cost (\$/lb U <sub>3</sub> O <sub>8</sub> )		
	Conventional mills	ISL facilities	Heap leach
GACT—Double Liners for Conventional Impoundments *	\$1.04		
GACT—Double Liners for Non-conventional Impoundments *	1.04	3.07	0.22
GACT—Maintaining Non-conventional Impoundment Sediments 100% Saturated	0.015	0.026	0.0013
GACT—Liners for Heap Leach Piles *			2.01
GACTs—Total for All Four	2.09	3.09	2.24
Baseline Facility Costs ** (EIA Section 6.2)	55.18	51.31	45.06

\* Liners required by 40 CFR part 192.  
 \*\* Based on a price of U<sub>3</sub>O<sub>8</sub> of \$55/lb.

Based on the information in Table 1, the four GACT-based standards represent about 4%, 6%, and 5% of the baseline cost (per pound of U<sub>3</sub>O<sub>8</sub>) at conventional, ISL, and heap leach uranium recovery facilities, respectively. The table shows that, at a market price of \$55 per pound, the baseline facility costs for a conventional mill are greater than the market price of uranium. However, since the liner requirements would have to be met under 40 CFR part 192, these costs are not actually being imposed by Subpart W. The only cost associated with the final rule is the cost of maintaining saturation in the non-conventional impoundments, which is minimal.

6. Public Engagement

During development of the proposed rule and throughout the public comment period, the EPA engaged with

stakeholders and sought public input. Subsequent to beginning the rulemaking process, the EPA entered into a settlement agreement in August 2009 with Colorado Citizens Against Toxic Waste (CCAT) and Rocky Mountain Clean Air Action. As part of the settlement agreement, the EPA agreed to:

- Provide three public presentations and a national webinar on the rulemaking;
- Conduct quarterly stakeholder conference calls on the status of the rulemaking; and
- Create a public Web site and post non-privileged records.

The EPA conducted public presentations in June 2009 in Cañon City, Colorado, near the Cotter Mill; in October 2009 in Rapid City, South Dakota, in conjunction with the Western Mining Action Network’s semi-annual

conference; and in May 2010 on lands of the Ute Mountain Ute Tribe in southeastern Utah, near the White Mesa Mill. The EPA also presented a national webinar in June 2010. Records of EPA’s quarterly stakeholder calls and non-privileged records regarding this Subpart W rulemaking are available at the following public Web site: <https://www.epa.gov/radiation/subpart-w-rulemaking-activity>.

In addition to the presentations specified in the settlement agreement, the EPA conducted presentations at numerous industry-sponsored events, particularly the annual uranium recovery workshop sponsored by the NRC and the National Mining Association (NMA). Beginning in 2009, the EPA provided regular updates on the Subpart W rulemaking at these annual workshops. The EPA also provided a presentation for NMA

officials in October 2009 and participated in NRC’s uranium recovery licensing workshop in January 2011.

The EPA also actively sought interactions with tribal stakeholders. Several current or proposed uranium recovery facilities are of interest to tribes. The White Mesa Mill is located just north of Ute Mountain Ute lands in southeastern Utah. The Oglala Sioux Tribe has been active in the renewal of the operating license for the Crow Butte ISL facility in northwestern Nebraska and the initial licensing of the proposed Dewey-Burdock ISL facility in southwestern South Dakota. The Navajo Nation has been active in the development of proposed ISL facilities in New Mexico.

The EPA conducted presentations at the Uranium Contamination Stakeholder Workshops in 2009 and 2010 in Gallup, New Mexico and Tuba City, Arizona, respectively. In addition to the presentations, the EPA also held

discussions with representatives from the Navajo EPA and the Hopi Tribe. In June 2014, after the proposed rule was published, the EPA gave a presentation for the National Tribal Air Association (NTAA) on the monthly NTAA/EPA policy call.

Concurrent with issuance of the 2014 proposed rule, the EPA sent letters to 53 tribal leaders offering consultation on the rule, consistent with the EPA’s “Policy on Consultation and Coordination with Indian Tribes.” Consultation is a process of meaningful communication and coordination between the EPA and tribal officials prior to the EPA taking actions or implementing decisions that may affect tribes. The Ute Mountain Ute Tribe responded and requested a formal consultation. The consultation was held in July 2014 between officials of the EPA’s Office of Radiation and Indoor Air in Washington, DC and officials from EPA Region 8 and the Tribe at

Tribal headquarters in Towaoc, Colorado (Docket No. EPA–HQ–OAR–2008–0218–0120).

The EPA has also met with individual stakeholder groups. Prior to publication of the proposed rule, the EPA met with representatives from CCAT, Uranium Watch, and the Sheep Mountain Alliance. Following publication of the proposed rule, the EPA met with the Southern Environmental Law Center. Concurrent with public hearings in September 2014, the EPA met with representatives from CCAT and the Energy Minerals Law Center. Following the public comment period, in November 2014 the EPA met with representatives from Uranium Watch and the Information Network for Responsible Mining (INFORM).

*B. Does this action apply to me?*

The regulated categories and entities potentially affected by the final standards are shown below in Table 2:

TABLE 2—INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Category	NAICS code <sup>1</sup>	Examples of regulated entities
Industry:		
Uranium Ores Mining and/or Beneficiating .....	212291	Area source facilities that extract or concentrate uranium from any ore processed primarily for its source material content.
Leaching of Uranium, Radium or Vanadium Ores .....	212291	Area source facilities that extract or concentrate uranium from any ore processed primarily for its source material content.

<sup>1</sup> North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this final action. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permit authority for the entity or your EPA regional representative as listed in 40 CFR 61.04 of subpart A (General Provisions).

*C. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this final action will also be available on the Internet. Following signature, a copy of this final action will be posted at the following address: <https://www.epa.gov/radiation/subpart-w-national-emission-standards-radon-emissions-operating-mill-tailings>. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same Web site.

*D. Judicial Review and Administrative Reconsideration*

Under CAA section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by March 20, 2017. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that “[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review.” This section also provides a mechanism for the EPA to reconsider the rule “[i]f the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the

outcome of the rule.” Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC West Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

**II. Background**

*A. What is the Agency’s legal authority for taking this action?*

Section 112(q)(1) of the Clean Air Act (CAA) requires that NESHAPs “in effect before the date of enactment of the Clean Air Act Amendments of 1990 [Nov. 15, 1990] . . . shall be reviewed and, if appropriate, revised, to comply with the requirements of subsection (d) of . . . section [112].” The EPA promulgated 40 CFR part 61, subpart W, “National Emission Standards for Radon Emissions from Operating Mill

Tailings,” (Subpart W) on December 15, 1989.<sup>4</sup> The EPA conducted this review of Subpart W under CAA section 112(q)(1).

Section 112(d) of the CAA requires the EPA to establish emission standards for major and area sources. A major source is any stationary source that emits or has the potential to emit 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAPs. An area source is a stationary source of HAP that is not a major source. For operating uranium byproduct material or tailings impoundments, the HAP of concern is radon-222 (hereafter referred to as “radon” or Rn-222). Radon emissions from operating uranium recovery facilities are far below the statutory thresholds<sup>5</sup> and EPA has not set alternative criteria for identifying major sources of radionuclide emissions; thus, all sources regulated under Subpart W are area sources (EPA-HQ-OAR-2008-0218-0001, 0002). See Section IV.A.2.

Section 112(q)(1) does not dictate how the EPA must conduct its review of those NESHAPs issued prior to 1990. Rather, it provides that the Agency must review, and, if appropriate, revise the standards to comply with the requirements of section 112(d). Determining what revisions, if any, are appropriate for these NESHAPs is best assessed through a case-by-case consideration of each NESHAP. As explained below, in this case, we have reviewed Subpart W and are revising the standards consistent with section 112(d)(5), which addresses standards for area sources. After our review, we determined it was appropriate to revise Subpart W to clarify the applicability of the rule to non-conventional impoundments and heap leach piles and promulgate standards that are more appropriate for controlling radon emissions at those sources, consistent with the requirements of CAA section 112(d)(5). All units regulated by Subpart W are area sources and we determined that promulgating GACT-based

standards under CAA section 112(d)(5) is appropriate for these sources.

For area sources, the Administrator has the discretion under CAA section 112(d)(5) to set standards based on GACT in lieu of maximum achievable control technology (MACT) under sections 112(d)(2) and (d)(3), which is required for major sources. Under CAA section 112(d)(5), the Administrator may elect to promulgate standards or requirements for area sources “which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants.” Consistent with section 112(d)(5), we are revising Subpart W to reflect GACT-based standards.

#### *B. What source category is affected by the final rule?*

The source category regulated under Subpart W, first defined in 1986, is facilities licensed to manage uranium byproduct material during and following the processing of uranium ores, commonly referred to as uranium mills and their associated tailings. Licenses are issued by the U.S. Nuclear Regulatory Commission (NRC) or NRC Agreement States. As promulgated in 1986 and 1989, Subpart W defines “uranium byproduct material or tailings” as “the waste produced by the extraction or concentration of uranium from any ore processed primarily for its source material content.”<sup>6</sup> Neither of these definitions is affected by this action. For clarity, in this action we refer to this source category by the term “uranium recovery facilities,” and we are adding this phrase to the definitions section of the rule. Use of this term encompasses the existing universe of facilities whose HAP emissions are currently regulated under Subpart W. Uranium recovery facilities process uranium ore to extract uranium. The HAP emissions from any type of uranium recovery facility that manages uranium byproduct material or tailings are subject to regulation under Subpart W. This currently includes three types

of uranium recovery facilities: (1) Conventional uranium mills; (2) ISL facilities; and (3) heap leach facilities. Subpart W requirements specifically apply to the affected sources at the uranium recovery facilities that are used to manage or contain the uranium byproduct material or tailings. Common names for these structures may include, but are not limited to, impoundments, tailings impoundments, tailings piles, evaporation or holding ponds, and heap leach piles. However, the name itself is not important for determining whether Subpart W requirements apply to that structure; rather, applicability is based on what these structures contain and the use of these structures to manage or contain uranium byproduct material or tailings.

#### *C. How does Subpart W regulate HAP emissions from the source category?*

Subpart W was initially promulgated on September 24, 1986 (51 FR 34056) and amended pursuant to a voluntary remand on December 15, 1989 (54 FR 51654). At the time of promulgation in the 1980s, the predominant form of uranium recovery was through the use of conventional mills. As promulgated in 1989, Subpart W contained two separate standards. The first standard applied to “existing” impoundments, *i.e.*, those in existence and licensed by the NRC (or its Agreement States) on or prior to December 15, 1989. Owners or operators of existing tailings impoundments were required to ensure that emissions from those impoundments did not exceed a radon (Rn-222) flux standard of 20 picocuries per meter squared per second (pCi/m<sup>2</sup>-sec). As stated at the time of promulgation: “This rule will have the practical effect of requiring the mill owners to keep their piles wet or covered” (54 FR 51689). Keeping the piles (impoundments) wet or covered with soil would reduce radon emissions to a level that would meet the standard. This is still considered an effective method to reduce radon emissions at all uranium byproduct material or tailings impoundments.

The method for monitoring for compliance with the radon flux standard was prescribed as Method 115, found at 40 CFR part 61, Appendix B. The owners or operators of existing impoundments were required to report to the EPA the results of the compliance testing for any calendar year by no later than March 31 of the following year.

There is currently one operating mill with impoundments that pre-date December 15, 1989, and two mills that are currently in standby mode. All of

<sup>4</sup> On April 26, 2007, Colorado Citizens Against Toxic Waste (CCAT) and Rocky Mountain Clean Air Action filed a lawsuit against EPA (EPA-HQ-OAR-2008-0218-0013) for EPA’s alleged failure to review and, if appropriate, revise NESHAP Subpart W under CAA section 112(q)(1). A settlement agreement was entered into between the parties in November 2009 (EPA-HQ-OAR-2008-0218-0020, 0021).

<sup>5</sup> Annual emissions of radon from a 40-acre impoundment, assuming a radon flux of 20 pCi/m<sup>2</sup>-sec, can be calculated to be approximately 2.5 Ci. The specific activity of radon is about 150,000 Ci/g. Reasonably anticipated emissions from sources subject to Subpart W do not approach the 10 tpy threshold established in CAA § 112(a)(1) to define major sources.

<sup>6</sup> Pursuant to the Atomic Energy Act of 1954, as amended, the Nuclear Regulatory Commission defines “source material” as “(1) Uranium or thorium or any combination of uranium or thorium in any chemical or physical form; or (2) Ores that contain, by weight, one-twentieth of one percent (0.05 percent), or more, of uranium or thorium, or any combination of uranium or thorium” (10 CFR 20.1003). For a uranium recovery facility licensed by the Nuclear Regulatory Commission under 10 CFR part 40, “byproduct material” means the “tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes” (10 CFR 20.1003 and 40.4.)

these impoundments are subject to Subpart W until they begin closure.

The second standard applied to “new” impoundments constructed after December 15, 1989. The requirements applicable to new impoundments were work practice standards that regulated either the size and number of impoundments, or the amount of tailings that may remain uncovered at any time. After December 15, 1989, “no new tailings impoundment can be built unless it is designed, constructed and operated to meet one of the following two work practices:

1. Phased disposal in lined tailings impoundments that are no more than 40 acres in area and meet the requirements of 40 CFR 192.32(a) as determined by the Nuclear Regulatory Commission. The owner or operator shall have no more than two impoundments, including existing impoundments, in operation at any one time.

2. Continuous disposal of tailings such that tailings are dewatered and immediately disposed with no more than 10 acres uncovered at any time and operated in accordance with § 192.32(a) as determined by the Nuclear Regulatory Commission.”

The basis of the work practice standards was to (1) limit the size of the impoundment, which limits the radon source; or (2) use the continuous disposal system, which prohibits large accumulations of dewatered uncovered uranium byproduct material or tailings, limiting the amount of radon released.

#### *D. What changes to Subpart W did we propose?*

Pursuant to CAA Section 112(d)(5), in the May 2, 2014 notice we proposed GACT-based standards for the affected sources at conventional uranium mills, ISL facilities and heap leach facilities. Subpart W has always applied to these sources; however, given the evolution of uranium recovery facilities over the last 20 years, we thought it appropriate to revise Subpart W to tailor the requirements of the NESHAP to the different types of facilities in existence at this time and reaffirm Subpart W’s applicability to these facilities. For the conventional impoundments the GACT-based standards were based upon the requirements established in 1989. We also proposed to revise Subpart W to add appropriate definitions, standards and other requirements that are more applicable to HAP emissions at these different types of uranium recovery facilities. Specifically, we proposed to:

- Remove monitoring requirements for impoundments constructed prior to December 15, 1989 and to have these “existing” impoundments demonstrate

compliance with the proposed GACT-based standards;

- clarify that any impoundment at a uranium recovery facility that contained uranium byproduct materials or tailings is regulated under Subpart W and subject to the liner requirements referenced at 40 CFR 192.32(a)(1), including “evaporation” or “holding” ponds;

- establish as GACT-based standards that these “non-conventional” or liquid-holding impoundments meet the design and construction requirements of 40 CFR 192.32(a)(1), with no size/area restriction or monitoring requirement, and that during the active life of the pond at least one meter of liquid be maintained in the pond;

- establish as GACT-based standards that heap leach piles meet the phased disposal management practice standard (which limits an owner/operator to no more than two operating heap leach piles of no more than 40 acres each at any time) and the design and construction requirements at 40 CFR 192.32(a)(1) as GACT-based standards, and maintain minimum moisture content of 30%;

- add a definition of “standby” to clarify the term and how it relates to the operational phase of an impoundment;

- amend the definition of “operation” of an impoundment so that it is clear when the owner or operator is subject to the requirements of Subpart W;

- add definitions of “conventional impoundment,” “non-conventional impoundment,” “heap leach pile,” “uranium recovery facility” and “heap leach pile operational life” to be consistent with the GACT-based standards;

- determine whether Subpart W adequately addresses protection from extreme weather events;

- revise 40 CFR 61.252(b) and (c) to accurately reflect that it is only 40 CFR 192.32(a)(1) that is applicable to Subpart W; and

- remove the phrase “as determined by the Nuclear Regulatory Commission” in 40 CFR 61.252(b)(1) and (2).

#### *E. Comments on the Proposed Rule*

The public comment period began on May 2, 2014 and was originally proposed to end on July 31, 2014. The comment period was extended by public request until October 29, 2014. We held two days of public hearings in Denver, CO on September 4 and 5, 2014. During the public comment period for the proposed rule, the EPA met with tribal leaders from the Ute Mountain Ute Tribe, consistent with the “EPA Policy on Consultation and Coordination with Indian Tribes”

(<http://www.epa.gov/tribal/forms/consultation-and-coordination-tribes>).

The consultation was held on July 10, 2014. The Tribe had numerous comments regarding the White Mesa uranium mill. Tribal land is several miles from the mill. The mill is the only operating conventional mill in the country, and the Tribe presented valuable information and comments for the rulemaking. The Tribe also raised enforcement issues that are concerns for the State of Utah and the EPA Region 8 office, but are not relevant to this rulemaking. The EPA has delegated to the State of Utah authority for implementation and enforcement of Subpart W (60 FR 13912, March 15, 1995).

The EPA received approximately 45 separate sets of comments on the proposed rule, including multiple submittals by the same author(s). The comments range in size from one page to several hundred pages, and in many cases contain dozens of individual comments. All told the EPA identified over 4,000 individual comments. A mass mailer that contains over one thousand signatures is also in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2008–0218). The docket also includes the transcripts of the two public hearings held in Denver, CO on September 4 and 5, 2014. All of the comments received are in the docket for this rulemaking. All comments can be accessed electronically through the Federal Document Management System (FDMS), available at <http://www.regulations.gov>. This Web site provides instructions on how to access the electronic docket. Some submittals may be duplicated in FDMS, as a commenter may have used several methods to ensure the comments were received, such as statement at a public hearing, fax, email, U.S. mail, or directly through FDMS.

There are two primary mechanisms by which we explain the issues raised in public comments and our reactions to them. First, we discuss broad or major comments in the following sections of this document. Second, we are including in the docket a document, accompanying this action, entitled “Summary of Public Comments and Responses.” The Response to Comments document addresses all other significant comments on the proposal. We gave all the relevant comments we received, whether written or oral, consideration in developing the final rule.

### **III. What final amendments are we issuing with this action?**

This action finalizes the EPA’s determinations pursuant to its review of



Subpart W under CAA section 112(q)(1) to “review, and if appropriate, revise” NESHAPs promulgated prior to November 15, 1990. After review of the comments we determined that commenters provided reasons and presented information supporting revision to certain aspects of the proposed rule. In this section we describe the final amendments to Subpart W for this action and identify revisions made to the proposed rule in response to comments.

#### A. Application of Generally Available Control Technologies (GACT) to Uranium Recovery Facilities

We determined that the management practices promulgated in 1989 for conventional impoundments constructed after December 15, 1989 remain suitable for controlling radon from uranium byproduct material or tailings. We also concluded that these management practices qualify as elements of GACT-based standards for these impoundments. We further determined that there are management practices which constitute generally available control technologies that could be applied to non-conventional impoundments and heap leach piles. The final rule establishes the following elements as GACT-based standards for conventional impoundments constructed after December 15, 1989, non-conventional impoundments and heap leach piles:

- Construction of all impoundments containing or managing uranium byproduct material in accordance with the requirements in 40 CFR 192.32(a)(1);
- Operation of conventional impoundments in accordance with either the phased disposal or continuous disposal method;
- Operation of non-conventional impoundments such that solid materials in the impoundment are not visible above the liquid level, to be verified by daily visual inspection and documented by digital photograph no less frequently than weekly; and
- Maintenance of heap leach piles that have completed their operational life but have not yet entered closure in accordance with the phased disposal method (piles no larger than 40 acres in area and no more than two such piles at any time).

For conventional impoundments constructed before December 15, 1989, we retained the radon flux standard originally promulgated in 1989, and retained the requirement that the impoundments comply with the construction requirements in 40 CFR 192.32(a)(1), notwithstanding the exemption in § 192.32(a)(1) for

impoundments constructed prior to the promulgation of 40 CFR part 192.

#### B. Definitions, References and Conforming Editorial Revisions

We are making revisions to several existing definitions and references, deleting a phrase and providing several new definitions. These revisions are:

- The definition of “operation” is revised as proposed;
- The definitions of “continuous disposal,” “dewatered,” “existing impoundment,” and “phased disposal” are revised to conform to the revised definition of “operation”;
- Definitions of “standby,” “conventional impoundment,” “non-conventional impoundment,” “heap leach pile,” “uranium recovery facility,” and “heap leach pile operational life” are added as proposed, with minor conforming changes;
- The reference in the 1989 rule at 40 CFR 61.252(b) and (c) is revised to 40 CFR 192.32(a)(1), as proposed, to clarify that the liner requirements are the portion of interest; as finalized, the reference to 40 CFR 192.32(a)(1) is included in § 261.252(a)(2)(i), (a)(2)(ii), (b) & (c) and the reference at § 61.252(c) in the 1989 rule is incorporated into § 61.252(a)(1) in the final rule;
- The phrase “as determined by the Nuclear Regulatory Commission” is eliminated from 40 CFR 61.252(b)(1) and (2), as proposed (§ 61.252(a)(2)(i) and (ii) in the final rule);
- The definition of “final closure” is added for completeness and clarity, in response to comments regarding the applicability of Subpart W; and
- The definition of “reclamation plan” is added to further clarify the concept of closure.

#### C. What are the recordkeeping, notification and reporting requirements?

New and existing affected sources are required to comply with the existing requirements of the General Provisions (40 CFR part 61, subpart A). The General Provisions include specific requirements for notifications, recordkeeping and reporting, including provisions for notification of construction and/or modification and startup as required by 40 CFR 61.07, 61.08 and 61.09.

We are also requiring that all affected sources maintain certain records pertaining to the design, construction and operation of conventional impoundments, non-conventional impoundments and heap leach piles. These records must be retained at the facility and contain information demonstrating that the impoundments and/or heap leach pile meet the

requirements in 40 CFR 192.32(a)(1), including but not limited to, all tests performed that prove the liner is compatible with the material(s) being placed on the liner. For non-conventional impoundments, this requirement also includes records showing compliance with the requirement to maintain liquid in the impoundment such that solid materials are not visible above the liquid.<sup>7</sup> Documents showing that the impoundments and/or heap leach pile meet the requirements in § 192.32(a)(1) are already required as part of the pre-construction application submitted under 40 CFR 61.07, so these records should already be available. Written and other records showing compliance with the liquid requirement for non-conventional impoundments can be created during the daily inspections of the tailings and waste retention systems required by the NRC (and Agreement States) under the inspection requirements of 10 CFR part 40, Appendix A, Criterion 8A.

Because we are retaining the radon flux standard for conventional impoundments in existence on December 15, 1989, we are also retaining the associated reporting requirements at 40 CFR 61.254 and these units must also comply with the revised recordkeeping requirements at 40 CFR 61.255, as applicable.

Because we are promulgating new recordkeeping requirements for uranium recovery facilities, we are required by the Paperwork Reduction Act (PRA) to prepare an estimate of the burden of such record-keeping on the regulated entity, in both cost and hours necessary to comply with the requirements. We have submitted the Information Collection Request (ICR) containing this burden estimate and other supporting documentation to the Office of Management and Budget (OMB). See Section VII.B for more discussion of the PRA and ICR.

We believe the record-keeping requirements promulgated today will not create a significant burden for operators of uranium recovery facilities. As described earlier, we are requiring retention of two types of records: (1) Records demonstrating that the impoundments and/or heap leach pile meet the requirements in § 192.32(a)(1) (e.g., the design and liner testing information); and (2) records showing that liquid is maintained to cover any

<sup>7</sup> The liquid requirement pertains to having the level of liquid cover any and all solid uranium byproduct material or tailings. We do not anticipate a large quantity of solid uranium byproduct material or tailings in these non-conventional impoundments (EPA-HQ-OAR-2008-0218-0088).

solid uranium byproduct material or tailings present in non-conventional impoundments.

Documents demonstrating that the affected sources comply with § 192.32(a)(1) requirements are necessary for the facility to obtain regulatory approval from the NRC (or an NRC Agreement State) and the EPA to construct and operate the affected sources (this includes any revisions during the period of operations). Therefore, these records will exist independent of Subpart W requirements and will not need to be continually updated as a result of this record-keeping requirement in Subpart W; however, we are including this record-keeping requirement in Subpart W to require that the records be maintained at the facility and available for inspection during its operational lifetime (in some cases the records might be stored at a location away from the facility, such as corporate offices). This might necessitate creating copies of the original records and providing a location for storing them at the facility.

Keeping a record to provide confirmation that liquid is maintained above the solid uranium byproduct material or tailings present in non-

conventional impoundments should also be relatively straightforward. This would involve visual inspection and documentation, such as written notes and digital photographs with embedded date and time and other identifying metadata, using photographic capabilities that are readily available, such as smartphones or small digital cameras. As noted earlier, NRC and Agreement State licenses require operators to inspect the facility on a daily basis. Only minimal effort will be necessary to make observations of saturation and record the information in inspection log books that are already kept on site and available to inspectors. Inspections for saturation can occur during the daily inspections that are already required by NRC and Agreement States. The final rule requires that operators record written observations daily and collect photographic evidence of liquid depth no less frequently than weekly. Beginning on the effective date of this final rule, digital photographs are to be uploaded on at least a monthly basis to the EPA's Subpart W Impoundment Photographic Reporting (SWIPR) system. If that system is unavailable, digital photographs are to

be retained by the facility and provided to the EPA or the authorized state upon request.

The final rule also includes a definition of "final closure" that refers to notification by the facility owner/operator. Subpart W applies to operating sources used to manage uranium byproduct material or tailings. Sources cease to be operating when they enter the closure process. The definition of "final closure" in the final rule clarifies that closure does not begin until the owner or operator provides written notification to the EPA and the NRC that the impoundment or heap leach pile is no longer used for its operational purpose and is being managed under an approved reclamation plan for that impoundment or pile, or the facility closure plan. Such notifications should involve limited effort on the part of facility owners or operators. A reclamation plan is required by NRC regulation and is not a new requirement under Subpart W.

We estimate the burden in hours and cost for uranium recovery facilities to comply with the proposed recordkeeping and notification requirements are as follows:

TABLE 3—BURDEN HOURS AND COSTS FOR RECORDKEEPING REQUIREMENTS  
[Annual figures except where noted]

Activity	Hours	Costs
Maintaining Records for the 40 CFR 192.32(a)(1) requirements .....	* 20	* \$1,430
Verifying saturation for non-conventional impoundments, including collecting and uploading digital photographs	291	14,650

\* These figures represent a one-time cost to the facility.

**IV. What is the rationale for our final decisions and amendments to Subpart W?**

*A. Legal Authorities and GACT*

1. What is the legal authority for GACT based standards and management practices in the final rule?

Section 112(q)(1) of the CAA requires that NESHAPs "in effect before the date of enactment of the Clean Air Act Amendments of 1990 [Nov. 15, 1990] . . . shall be reviewed and, if appropriate, revised, to comply with the requirements of subsection (d) of . . . section [112]." The EPA promulgated 40 CFR part 61, subpart W, "National Emission Standards for Radon Emissions from Operating Mill Tailings," ("Subpart W") on December 15, 1989.<sup>8</sup> The EPA conducted this

review of Subpart W under CAA section 112(q)(1).

Section 112(d) establishes the requirements for emission standards for HAP promulgated under section 112. It establishes different requirements for major sources and area sources. A major source is any stationary source that emits or has the potential to emit 10 tpy or more of any single HAP or 25 tpy or more of any combination of HAPs. An area source is a stationary source of HAP that is not a major source. See Sections II.B and IV.A.2 for discussion of area sources as they relate to Subpart W.

Pursuant to CAA section 112(d), standards for major sources "shall require the maximum degree of reduction in emissions of the hazardous air pollutants . . . that the Administrator . . . determines is

achievable." For area sources, the Administrator has the discretion under CAA section 112(d)(5) to set standards based on GACT in lieu of MACT. Specifically, CAA section 112(d)(5) provides that the Administrator may elect to promulgate standards or requirements for area sources "which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants."

Section 112(q)(1) does not dictate how the EPA must conduct its review of those NESHAPs issued prior to 1990. Rather, it provides that the Agency must review, and if appropriate, revise the standards to comply with the requirements of section 112(d). Determining what revisions, if any, are appropriate for these NESHAPs is best assessed through a case-by-case consideration of each NESHAP. In other rulemakings, the EPA has determined that GACT standards are appropriate for

<sup>8</sup> On April 26, 2007, CCAT and Rocky Mountain Clean Air Action filed a lawsuit against the EPA (EPA-HQ-OAR-2008-0218-0013) for the EPA's alleged failure to review and, if appropriate, revise NESHAP Subpart W under CAA section 112(q)(1).

A settlement agreement was entered into between the parties in November 2009 (EPA-HQ-OAR-2008-0218-0020, -0021).

a number of different area sources, including, for example, industrial, commercial and institutional boilers (promulgated at 40 CFR part 63, subpart JJJJJ) and oil and natural gas production facilities (promulgated at 40 CFR part 63, subpart HH). Using a GACT evaluation, the EPA has historically established both emission standards and management practices, as appropriate.

As explained below, in this case, we have reviewed Subpart W and are revising the standards consistent with section 112(d)(5), which addresses standards for area sources. After our review, we determined it was appropriate to revise Subpart W to clarify the applicability of the rule to non-conventional impoundments and heap leach piles and promulgate standards that are more appropriate for controlling radon emissions at those sources. All units regulated by Subpart W are area sources and we determined that promulgating GACT-based standards under CAA section 112(d)(5) is appropriate for these sources. Consistent with section 112(q)(1) we are revising Subpart W to comply with the requirements in section 112(d) relating to emission standards for area sources and are thus revising the Subpart W standards to reflect GACT-based standards.

## 2. What key comments did we receive on our legal authorities and the GACT approach?

We received several comments challenging our use of GACT for this rulemaking. Commenters specifically asserted that the EPA may not set GACT-based standards for sources subject to Subpart W and challenged our conclusion that facilities subject to Subpart W are area sources.

Commenters further argued that the work practices instituted for conventional impoundments in 1989, which we are finalizing today as GACT-based standards, are contrary to CAA section 112(h), which allows the EPA to promulgate work practices in lieu of MACT standards only when “it is not feasible in the judgment of the Administrator to prescribe or enforce an emission standard.”

We summarize below a number of comments received on this topic and present our responses. Additional comment responses on this topic appear in the Response to Comments document in the docket for this rulemaking.

*Comment:* A commenter argued that uranium recovery operations should be considered, by definition, major sources of hazardous air pollutants and should be subject to major source requirements. The commenter further stated that the

EPA’s document Background Information for Proposed Area Source Standards is misleading because it uses the standard major source threshold at CAA section 112(a)(1), that any stationary source that emits or has the potential to emit 10 tpy or more of any single HAP or 25 tpy or more of any combination of HAPs, to support its conclusion that uranium recovery facilities regulated under Subpart W are area sources. The commenter stated that radon is not measured in tpy and that the CAA section 112 threshold of 10 or 25 tpy was not intended to apply to radon or other radionuclides.

*Response:* Under section 112(a)(1) of the CAA major sources are defined as stationary sources or groups of stationary sources that emit, or have the potential to emit, any single HAP at a rate of 10 tpy or more, or 25 tpy or more of any combination of HAP. An area source, in turn, is any stationary source of HAP that is not a major source. CAA section 112(a)(2). The statute also allows the EPA to establish lower thresholds, or for radionuclides to establish different criteria based on the characteristics of the air pollutant and relevant factors, but the statute is clear on its face that the EPA is not required to set alternative criteria. CAA section 112(a)(1). In the absence of alternative criteria, the statutory criteria of 10 tpy of a single HAP or 25 tpy of a combination of HAP applies, and any source that does not meet or exceed those thresholds is an area source. By allowing the EPA to set different criteria only for radionuclides, the statute implicitly recognizes that an alternative to the statutory thresholds based on tpy may be appropriate for sources of radionuclides. Nonetheless, the statute neither requires the EPA to set alternative criteria for defining major sources of radionuclides, nor obligates the EPA to designate any or all radionuclide sources as major sources. In sum, the statute explicitly leaves open the possibility that all sources of radionuclides will be regulated as area sources unless the EPA decides to establish alternate criteria. Moreover, even if the EPA had decided to set alternate criteria, nothing in the CAA would have required the EPA to establish criteria that would have the effect of making some sources that manage uranium byproduct material or tailings major sources of HAP. Thus, there is no basis for the commenter’s assertion that uranium recovery operations should be considered, by definition, major sources of HAP.

In addition, regulating sources that manage uranium byproduct material or tailings as area sources does not

constrain the EPA’s regulatory options. For area sources, the EPA can set GACT standards under CAA section 112(d)(5) or MACT standards under CAA section 112(d)(2). EPA’s decision to retain this flexibility by regulating these sources as area sources is reasonable and consistent with the discretion given to the EPA by the statutory text.

It is also worth noting that, under Subpart W, radon emissions from sources that manage uranium byproduct material or tailings are regulated regardless of whether they qualify as major or area sources. For source categories not regulated before 1990, the EPA has discretion to decide whether to list and thus whether to regulate area sources. Radon emissions from uranium byproduct material or tailings, however, were regulated prior to 1990 and CAA section 112(q) explicitly provides that such standards remain in force and effect after the effective date of the 1990 CAA Amendments. The distinction between major and area sources thus does not affect whether sources subject to Subpart W are regulated under CAA section 112. Nothing in CAA section 112(q)(1) or CAA section 112(d) limits EPA’s discretion to set standards under CAA section 112(d)(5), for sources regulated prior to the 1990 CAA Amendments whose emissions do not exceed the major source threshold established by Congress.

*Comment:* Commenters stated that the EPA must establish a source category pursuant to CAA section 112(c)(1) before promulgating CAA section 112(d) standards. One of these commenters cites to a 2007 EPA rulemaking which stated that listing pursuant to section 112(c) is a critical aspect and a condition precedent to issuing CAA section 112(d)(5) standards. Commenters also argued that the EPA must determine all HAPs present at uranium recovery facilities before the EPA can establish a source category, develop criteria to differentiate between major and area sources of radionuclides, and promulgate emission standards, whether MACT or GACT.

Another commenter asserted that because CAA section 112(q) requires pre-1990 regulations to be reviewed and, if appropriate, revised in accordance with the requirements of subsection (d), the revision must comply with all applicable requirements in CAA section 112, including all parts of CAA section 112 enacted as part of the 1990 CAA Amendments.

One commenter also argued that the EPA must establish a source category or subcategory before promulgating standards under CAA section 112(d)(5) for facilities licensed to manage

uranium byproduct materials. The comments state that the EPA has not complied with the requirements of CAA section 112 and has not taken the requisite preliminary actions and evaluations to support establishing revised standards for uranium recovery facilities, specifically GACT. Another commenter stated that the EPA has no basis for setting GACT standards in lieu of MACT standards.

*Response:* The EPA originally promulgated Subpart W in 1989, before Congress enacted the 1990 CAA Amendments. The 1990 Amendments introduced the requirement to list major and area sources of HAPs. See CAA sections 112(c)(1) & (c)(3), 42 U.S.C. 7412(c)(1) & (c)(3). The 1990 Amendments also added CAA section 112(q), which explicitly provides that section 112 standards in effect prior to the date of enactment of the 1990 CAA Amendments shall remain in force and effect after that date. CAA section 112(q)(1) also provides that: “Each [standard in effect before the enactment of the CAA Amendments of 1990] shall be reviewed and, if appropriate, revised to comply with the requirements of subsection (d) of this section . . .” In sum, Congress clearly intended that (1) standards promulgated prior to 1990 remain in effect; and (2) the EPA may update the standards, as appropriate. However, there is no indication that Congress intended to require that the EPA go through the process of listing source categories that were subject to regulations prior to 1990 and thus, effectively already “listed.” CAA section 112(c)(4) provides that, “The Administrator may, in the Administrator’s discretion, list any category or subcategory of source previously regulated under this section as in effect before November 15, 1990.” The EPA reviewed Subpart W pursuant to section 112(q)(1) and has not listed uranium recovery operations pursuant to section 112(c).

The EPA disagrees with the commenters’ assertions that the EPA must list the regulated source category pursuant to section 112(c) before revising the existing Subpart W. Section 112(q)(1), on its face, does not require the EPA to list such sources pursuant to subsection (c) as part of a section 112(q) review. It does not contain any cross reference to the listing provisions of section 112(c). Instead, section 112(q) requires revision, if appropriate, in accordance with subsection (d)—the subsection that governs standard setting under section 112. Moreover, section 112(c)(4) explicitly grants the Administrator discretion to decide whether or not to list categories and

subcategories of sources regulated under section 112 prior to the 1990 CAA Amendments. Thus, neither of the provisions addressing standards promulgated prior to the 1990 CAA Amendments, nor any other statutory provision, support the commenters’ assertion that listing under section 112(c) is a necessary part of a section 112(q) review.

There is also no basis for commenters’ statements that the EPA must determine all HAPs present at uranium recovery facilities and develop criteria to differentiate between major and area sources of radionuclides before it can promulgate emission standards, whether MACT or GACT. The EPA’s task under section 112(q) is to review and, if appropriate, revise standards in effect before the date of enactment of the 1990 CAA Amendments. Prior to the 1990 CAA Amendments, section 112 standards were promulgated for individual pollutants and Subpart W only establishes standards for radon resulting from management of uranium byproduct material or tailings at uranium recovery operations. The EPA’s obligation under section 112(q) therefore is limited to reviewing and, if appropriate, revising standards for radon resulting from management of uranium byproduct material or tailings at uranium recovery operations. The statutorily required review does not encompass listing the source category under section 112(c) or evaluating HAPs not previously regulated under the subpart being reviewed. As explained in the previous response, the statute also does not require the EPA to set alternate criteria for distinguishing between major and area sources of radionuclides.

The commenter’s reliance on a 2007 rulemaking is misplaced. In that rulemaking, the EPA promulgated NESHAPs for the first time for the identified source categories. The present rulemaking is governed by CAA section 112(q)(1), which only requires that the review and revision comply with the standard setting requirements of subsection (d). As explained above, the section 112(q)(1) review does not require listing the source category under section 112(c). The 2007 rulemaking set new standards and was not subject to the narrow review requirements of CAA section 112(q)(1). Further, CAA section 112(c)(4) explicitly provides the EPA with discretion regarding whether to list source categories regulated prior to the 1990 CAA Amendments. CAA section 112(c)(4) applies to the sources subject to Subpart W but was not applicable to the sources impacted by the 2007 rulemaking. For these reasons, the

statements made in the 2007 rulemaking are inapposite.

The commenter’s assertion that the EPA must revise Subpart W to comply with all provisions of section 112 is also based on an overly broad reading of CAA section 112(q)(1). The statute only instructs the EPA to “review[ ] and, if appropriate, revise[ ], to comply with the requirements of subsection (d) of this section . . .” It does not require the EPA to revise the pre-1990 rules to comply with every provision in the section 112 CAA Amendments of 1990. Indeed, to read section 112(q)(1) as requiring the EPA to revise the rules to comply with all provisions in section 112 would be to read the reference to subsection (d) out of the statute.

Finally, listing a source category under section 112(c) is not a pre-requisite to establishing GACT standards for area sources as part of a section 112(q) review. As explained in the previous response, section 112(d)(5) allows the EPA to set GACT instead of MACT standards for area sources. Specifically, CAA section 112(d)(5) provides that with respect only to categories and subcategories of area sources listed pursuant to section 112(c), the Administrator may, in lieu of setting standards under sections 112(d)(2) and 112(f), decide to promulgate standards based on generally available control technologies. Such standards are commonly referred to as GACT standards.

CAA section 112(d)(5) is ambiguous to the extent that it is not clear whether it provides that the EPA may set GACT standards “only” for “area sources” or whether it also prohibits the EPA from setting section 112(d)(5) GACT standards for area sources regulated under section 112 but not listed pursuant to section 112(c)—that is, area sources that are regulated pursuant to section 112 standards promulgated before the 1990 CAA Amendments but not added to the section 112(c) list. For the reasons explained below, the EPA does not interpret section 112(d)(5) as limiting its discretion to promulgate GACT standards as part of a section 112(q) review simply because the area source category has not been added to the section 112(c) list.

As an initial matter, the specific statutory provisions addressing section 112 standards that pre-dated the 1990 Amendments appear in sections 112(q)(1) and 112(c)(4). As discussed above, these provisions require the EPA to review and, if appropriate, revise such standards to comply with the requirements of subsection (d) and also establish that the EPA has discretion to decide whether or not to list source

categories under section 112(c). In the event of any conflict with other more general provisions in section 112, the more specific provisions of sections 112(q)(1) and 112(c)(4) govern.

The general standard setting obligation in section 112(d)(1) also provides helpful context. Specifically, CAA section 112(d)(1) states that “The Administrator shall promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources of hazardous air pollutants listed for regulation pursuant to subsection (c) of this section . . .” Section 112(d)(1) grants the EPA authority to set emission standards under both section 112(d)(2) (MACT standards) and section 112(d)(5) (GACT standards). Like section 112(d)(5), it cross references the listing provision of subsection (c). Neither provision explicitly addresses how it applies in the context of a section 112(q) review. And neither provision explicitly overrides either the section 112(q) review requirements or the discretion granted to the Administrator under section 112(c)(4). Therefore, for standards promulgated prior to the 1990 CAA Amendments, it is reasonable for the EPA to interpret sections 112(d)(1) and (d)(5) to not require listing pursuant to § 112(c) before the EPA can review the standards under section 112(q)(1) and, if appropriate, revise them to comply with subsection (d). In contrast, if the EPA were to take the approach suggested by commenters, and read the cross references to subsection (c) in sections 112(d)(1) and 112(d)(5) as a limitation on the EPA’s authority under section 112(q) to revise standards to comply with subsection (d) it would be inconsistent with CAA sections 112(q)(1) and 112(c)(4).

Given the statutory context outlined above, for this CAA section 112(q)(1) review, it is reasonable for the EPA to interpret CAA section 112(d)(5) as restricting the EPA’s ability to set GACT standards to “only area sources,” but not prohibiting the EPA from setting GACT standards as part of a section 112(q) review simply because the area source category is not listed pursuant to subsection (c).

*Comment:* Several commenters argued that the EPA improperly proposed to promulgate design and work practice standards in lieu of emissions standards. Specifically, commenters stated that the EPA cannot promulgate design and work practice standards without the Administrator first making a finding pursuant to CAA section 112(h) that emission standards are not feasible. Commenters took the position

that the EPA has not and cannot make a finding pursuant to CAA section 112(h) that radon emissions standards are not feasible at uranium recovery facilities. These and another commenter assert that the EPA has not and cannot make the “not feasible” showing, so the EPA must promulgate an emissions standard.

One of these commenters stated that the EPA has no legal basis for the promulgation of a design, equipment, work practice, or operational standard, or combination thereof, in lieu of a radon emission standard, because design, equipment, work practice, or operational standards are meant to supplement, not replace, a standard that places specific numerical limitations on HAP emissions. The commenter also asserts that the EPA has no legal basis for eliminating the emission standard for existing mill tailings impoundments.

The other commenter pointed to text from the legislative history of the 1990 CAA Amendments and stated that work practice standards must achieve the same or greater level of emissions reduction as a numerical emission standard. The commenter argues that radon emissions will be higher under the GACT standards than they would be under a numerical emission standard and therefore the EPA should promulgate an emission standard.

*Response:* The EPA disagrees with these comments. The statute does not require the EPA to make a finding pursuant to CAA section 112(h) prior to promulgating management practices for area sources pursuant to section 112(d)(5). While section 112(d)(2) requires the EPA to make such a finding prior to setting work practice standards in lieu of an emission standard, section 112(d)(5) contains no such requirement.

Instead, CAA section 112(d)(5) provides the EPA with discretion regarding the type of standards it sets for area sources by permitting the EPA to set standards or requirements “which provide for the use of generally available control technologies or management practices” (42 U.S.C. 7412(d)(5)). The EPA determined that the management practices required in this final rule constitute generally available management practices and effectively control radon emissions from conventional impoundments constructed after December 15, 1989, non-conventional impoundments and heap leach piles.

Because CAA section 112(d)(5) provides the EPA with the option of establishing management practices, the EPA was not required to make a showing under CAA section 112(h) that an emissions standard is not feasible

before we set management practices. Further, CAA section 112 does not provide that management practices must supplement emission standards; the EPA may set management practices to control emissions pursuant to CAA section 112(d)(5).

With respect to existing conventional impoundments in existence on December 15, 1989, the EPA is retaining the emissions standard originally promulgated in 1989. During the comment period, the EPA learned that the information on which it relied when proposing to remove the emission standard requirement for existing conventional impoundments designed or constructed prior to December 15, 1989 was not accurate. Because the conventional impoundments in existence on December 15, 1989 are constructed in such a way that they are unable to comply with the standards being promulgated for conventional impoundments constructed after December 15, 1989, the EPA determined that it is appropriate to retain the emissions standard and monitoring requirement for conventional impoundments in existence on December 15, 1989. Because these units have been subject to a radon flux standard of 20 pCi/m<sup>2</sup>-sec since 1989, this method of compliance is generally available and effectively regulates radon emissions from these units.

The EPA evaluated all types of units regulated by Subpart W: Conventional impoundments in existence as of December 15, 1989, conventional impoundments constructed after December 15, 1989, non-conventional impoundments, and heap leach piles. Each type of unit has different characteristics. Also, not all units were subject to the same requirements at the time of their construction, and the feasibility of compliance with emissions standards and/or management practices also varies between types of units. The EPA took these variations into consideration when we conducted our GACT analysis for each type of unit. Because the three remaining conventional impoundments in existence as of December 15, 1989 were subject to different construction requirements than units constructed after that date, and are not amenable to the management practices established in 1989 for those newer units, different standards are appropriate.

The legislative history language referenced by the commenter is concerned with the stringency of work practice standards promulgated under CAA section 112(h), when an emissions standard is not feasible. This passage of the legislative history is not discussing

the stringency of management practices promulgated under CAA section 112(d)(5) and thus is not relevant. Further, the commenter's claim that radon emissions will be higher under the GACT-based standards than they would be under a numerical emission standard is speculative. The commenter has not shown that the management practices promulgated in Subpart W will not effectively result in the same emissions reductions that would be achieved if the EPA had set a MACT standard under CAA section 112(d)(2). The GACT-based standards finalized in the rule will effectively control radon emissions from uranium byproduct material or tailings.

*Comment:* Several commenters challenged the EPA's authority to regulate impoundments associated with management of process liquids or effluents, referred to as non-conventional impoundments in the Subpart W rulemaking. One commenter submits that Subpart W does not apply to evaporation ponds at currently operating and future operating uranium recovery facilities, specifically in-situ facilities, because of the significant amount of process or waste water present. This and another commenter assert that evaporation ponds should not be regulated in Subpart W because the liquid cover substantially eliminates radon emissions. The second commenter further supports excluding evaporation ponds because the original 1989 rulemaking stated that science did not support the EPA exercising jurisdiction over fluid retention impoundments.

This commenter similarly argues that the EPA has no legal or regulatory bases to apply Subpart W to evaporation ponds at uranium recovery facilities. Further, the commenter states that after 20 years of consistent interpretation that Subpart W is only applicable to uranium mill tailings impoundments, the EPA is now asserting that Subpart W applies to evaporation ponds at in-situ recovery and conventional mill tailings facilities. The commenter argues that the EPA's position is inconsistent with the language and the rulemaking history associated with Subpart W since the regulations discuss uranium mill tailings "piles" and the rulemaking record states that the radon cover requirements in Subpart W's work practice standards are not intended to apply to such fluid retention impoundments.

The commenter also challenges that evaporation ponds are not covered by Subpart W because the specific examples in the regulations do not include evaporation ponds.

Another commenter argues that the liquid impoundments should not be regulated as tailings impoundments and should not be subject to 40 CFR part 192.

Alternatively, one commenter supported the EPA's confirmation that ISL facilities and liquid impoundments are subject to the EPA's CAA NESHAP jurisdiction. The commenter also stated that where the rule does not include emissions limits confirmed by monitoring and reporting requirements, the EPA has not carried out its CAA duty to minimize or eliminate radon emissions.

*Response:* Non-conventional impoundments (which include evaporation and holding ponds) are associated with all types of uranium recovery facilities, but especially ISL facilities. Non-conventional impoundments receive liquids containing uranium byproduct material or tailings from conventional milling, ISL operations or heap leach piles and the uranium byproduct material or tailings may be suspended or dissolved in the liquids. Some portion of the material will precipitate out and settle on the bottom of the impoundment. In fact, the liquid itself constitutes uranium byproduct material or tailings because it is a waste from the concentration or extraction process.

Commenters' arguments that the EPA lacks authority to regulate non-conventional impoundments lack merit. As an initial matter, commenters do not and could not support their assertion that the EPA lacks legal authority to regulate these impoundments. Radionuclides, including radon, are listed as HAPs in CAA section 112(b)(1), and the EPA has authority under sections 112(d) and 112(q) to regulate radionuclide emissions from sources that manage uranium byproduct materials or tailings.

In addition, commenters' alternate arguments, that these impoundments are not currently and should not be regulated by Subpart W, are incorrect. As promulgated in 1989, Subpart W requirements specifically apply to the structures at the uranium recovery facilities that are used to manage or contain the uranium byproduct material or tailings during and following the processing of uranium ores. 40 CFR 61.250. Common names for these structures may include, but are not limited to, impoundments, tailings impoundments, evaporation or holding ponds, and heap leach piles. However, the name itself is not important for determining whether Subpart W requirements apply to that structure; rather, applicability is based on what

these structures contain. Uranium byproduct material or tailings produced by ISL is covered by the definition of uranium byproduct material or tailings included in the 1989 Subpart W NESHAP, which is not altered by this final rule.

The EPA understood that there was previously some confusion regarding the applicability of Subpart W to different units that manage uranium byproduct material or tailings, including impoundments and evaporation ponds at ISL facilities (non-conventional impoundments) and heap leach facilities. The EPA also acknowledges that the provisions of the 1989 rule applied imperfectly to these units. The industry is shifting toward ISL as the dominant method of uranium recovery and, while it is not expected to be as significant a source of radon emissions as conventional impoundments, it is reasonable for the EPA, as part of this section 112(q) review, to clarify that the standards in Subpart W apply to non-conventional impoundments. To eliminate any potential confusion, the final rule reaffirms that Subpart W continues to regulate radon emissions from all management of uranium byproduct material or tailings at uranium recovery facilities. Subpart W has always applied to these units; this final rule clarifies that applicability and confirms that these impoundments are covered by Subpart W by establishing management practices tailored to non-conventional impoundments.<sup>9</sup>

The EPA has authority to interpret its own regulations, *Auer v. Robbins*, 519 U.S. 452 (1992), and may clarify its interpretation when justified. In this rulemaking, the EPA did not revise its interpretation of Subpart W, rather we clarified the applicability of the regulations. Moreover, the EPA also provided notice and opportunity for comment on these clarifications.

Commenters incorrectly state that evaporation ponds are not covered by Subpart W because evaporation ponds are not used as an example in the regulation. Similarly, commenters' claims that the radon cover requirements are not intended to apply

<sup>9</sup>Note that the BID supporting the 1989 final rule stated: "The licensed uranium mill tailings source category comprises the tailings impoundments and evaporation ponds created by conventional acid or alkaline leach processes at uranium mills licensed by the Nuclear Regulatory Commission (NRC) or the Agreement States" (BID Volume 2, Risk Assessments, EPA/520/1-89-006-1, page 9-1, emphasis added). The risk assessment evaluated the contribution of evaporation ponds to total radon emissions at some, but not all, of the operating and standby mills. If allowed to dry out, evaporation ponds could represent a non-negligible portion of the overall radon emissions subject to control under Subpart W. See Tables 9-2, 9-3, 9-28.

to fluid retention impoundments is inaccurate.<sup>10</sup> As explained previously, the determining factor of whether evaporation ponds are subject to Subpart W and whether the radon cover requirements apply is whether the unit contains uranium byproduct material or tailings. Since promulgated in 1989, Subpart W has applied to facilities licensed to manage uranium byproduct material or tailings; units that manage uranium byproduct material or tailings must comply with the applicable GACT-based standard.

In addition, to the extent commenters are challenging the EPA's interpretation of the applicability provisions in 40 CFR part 192, such comments are beyond the scope of this rulemaking and the EPA has no obligation to respond. This rulemaking addresses only Subpart W. The EPA's May 2, 2014 proposal did not reopen or take comment on any aspects of part 192. The applicability provisions of part 192 appear at 40 CFR 192.00. Subpart W does not expand the scope of applicability of part 192 as liners meeting the requirements at 40 CFR 192.32(a)(1) are already mandated by other regulations (79 FR 25407).

In response to one commenter's argument that Subpart W should not regulate evaporation ponds at ISL facilities because of the amount of water present in the ponds, the EPA disagrees. While the EPA agrees that the presence of sufficient liquid significantly reduces the radon emissions, that is not itself a reason to exclude evaporation ponds from regulation as a pond may still contain uranium byproduct material or tailings, which have the potential to emit radon. As stated above, the presence of uranium byproduct material or tailings in the pond determines whether the pond is regulated by Subpart W. The management practices the EPA is promulgating in Subpart W ensure that the radon emissions are continuously effectively controlled. The EPA requires that owners and operators of non-conventional impoundments ensure that the uranium byproduct material or tailings remains saturated, meaning that the material is covered in liquid, which will effectively control

radon emissions from these impoundments.

The EPA acknowledges and appreciates the commenter's support of the EPA's clarification that uranium in-situ leach facilities are subject to Subpart W. The EPA's response to the comment regarding the requirement to establish emissions limits confirmed by monitoring and reporting requirements is contained in the response to the previous comment.

*Comment:* Commenters questioned the appropriateness of including groundwater protection requirements in a NESHAP promulgated under the CAA since they do not affect air pollution. Further, one commenter added that the rule is unnecessary because it is designed to regulate HAPs yet it incorporates groundwater protection standards. The commenters stated that the additional requirements for fluid retention impoundments imposed by the imposition of 40 CFR 192.32(a)(1) and, by extension 40 CFR 264.221, are not justified.

Both commenters asserted that if the NRC believed that the imposition of the part 192 requirements were justified, the NRC would have explicitly referenced 40 CFR 192.32(a)(1) and by extension 40 CFR 264.221 in 10 CFR part 40 Appendix A, but it does not.

Alternatively, another commenter asserted that the EPA cannot allow a situation where the reduction of radon emissions comes at the expense of increased pollution of the groundwater or surface water. The commenter is concerned that the rule works at cross-purpose with 40 CFR part 192.

*Response:* The EPA may evaluate the non-air quality impacts of rules issued under CAA section 112. CAA section 112(d)(2) explicitly provides that the EPA has authority to consider non-air quality health and environmental impacts when promulgating standards under that section. For area sources, the EPA may promulgate standards under CAA section 112(d)(5) in lieu of CAA section 112(d)(2). Since the CAA provides for the EPA to consider such impacts under CAA section 112(d)(2), it is reasonable for the EPA to consider such impacts under CAA section 112(d)(5). Further, the CAA does not prohibit the EPA from considering non-air quality health and environmental impacts for CAA section 112(d)(5) standards. Additionally, we believe the Legislative History of the CAA Amendments of 1990 provides for the EPA generally taking environmental protection into account when promulgating standards for area sources (Senate Report Number 101-228, December 20, 1989).

Subpart W does not regulate groundwater or establish groundwater protection standards. Groundwater contamination is controlled by pre-existing regulations prepared under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA). During Subpart W rule development, the EPA considered the other regulations that impact sources subject to Subpart W and understood that surface impoundments subject to Subpart W are also subject to the standards in 40 CFR part 192 and part 264, subpart K. The part 192 groundwater protection regulations and liner requirements independently apply to the units subject to Subpart W. Through part 192 and part 264, subpart K, requirements were already in place at the time Subpart W was originally promulgated to protect groundwater from sources that manage uranium byproduct material or tailings. As the EPA explained in 1986, "potential effects of various alternatives on ground water were considered as part of the analysis of the impacts of this rule, since EPA has a responsibility to consider the impacts that its rules may have on the total environment. In part, this is done to ensure that regulations do not control pollution in one environmental medium only to degrade another" (51 FR 34058-34059). See also 54 FR 51680.

The EPA has considered the potential effects on groundwater from industry practices under this rule. The EPA also considered the separate, already existent, groundwater protection requirements when initially developing Subpart W. The EPA recognized that if water cover is maintained or expanded in order to limit radon emissions to the atmosphere, the potential for impacting groundwater increases because of the greater hydraulic head. It thus reasonably considered the extent to which existing requirements would limit potential groundwater impacts in determining reasonable management practices to limit radon emissions to the ambient air.

Additionally, the liner requirements have a direct connection to the effectiveness of Subpart W in limiting radon emissions from uranium byproduct material or tailings. It is well established that moisture reduces the rate of radon emanation. An unlined or poorly lined impoundment is more likely to lose moisture through the bottom of the impoundment. This not only increases the potential for ground water contamination, but increases the potential for the uranium byproduct material or tailings in the impoundment to dry out, thereby increasing radon emissions. Thus, the liner requirements

<sup>10</sup> In amending 40 CFR part 192 pursuant to an MOU with NRC, EPA stated the following in response to comments that evaporation ponds should remain open after emplacement of the final radon barrier: "EPA reiterates that the Agency does not intend the expeditious radon cover requirements to extend to areas where evaporation ponds are located, even if on the pile itself, to the extent that such evaporation pond is deemed by the implementing agency (NRC or an affected Agreement State) to be an appropriate aspect to the overall remedial program for the particular site" (emphasis added) (58 FR 60354, November 15, 1993).



boost the impoundment's ability to retain moisture and continue to control radon emissions. Because the liner requirements directly relate to the effectiveness of controlling radon emissions by retaining moisture and because the EPA considered the existing groundwater protection standards when evaluating the non-air environmental impact of using water to control air emissions, it was appropriate to acknowledge those standards and incorporate them into Subpart W. Further, nothing in this final action expands the applicability of 40 CFR part 192 to sources that would not otherwise be covered by part 192. See also Section IV.F.1.b.

Comments on the NRC regulations contained in 10 CFR part 40 Appendix A are beyond the scope of this rulemaking and, in any event, the regulations in 10 CFR part 40 Appendix A speak for themselves. In 10 CFR part 40 Appendix A, the NRC references and recognizes that the standards promulgated by EPA in 40 CFR part 192 achieve the minimum level of stabilization and containment of the sites concerned and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with the sites. Additionally, 10 CFR part 40 Appendix A incorporates the basic groundwater protection standards imposed by the EPA in 40 CFR part 192 which apply during operations and prior to the end of closure. 10 CFR part 40 Appendix A requires groundwater monitoring to comply with these standards.

In response to the other commenter, the EPA considered the regulations that independently apply to sources subject to Subpart W. The EPA recognized that the scope of units required to operate with liners pursuant to part 192 is consistent with the Subpart W regulations. Subpart W does not lessen the effectiveness of part 192.

*Comment:* Commenters concurred with the EPA's authority under Section 112 of the CAA to regulate radionuclide emissions at holding or evaporation ponds at conventional mills, at ISL facilities and at heap leach facilities. However, the commenters contend that the EPA should not only regulate uranium byproduct material or tailings in conventional impoundments, liquid effluent ponds, and heap leach piles, but should also regulate the large amounts of radon emitted from wellfields and other parts of ISL operations. One commenter used the Smith Ranch-Highland operation in Wyoming as an example.

The commenters also advocated for the EPA expanding the scope of operations covered by Subpart W at heap leach facilities. Specifically, the commenters encouraged the EPA to regulate radon emissions from the time ore is placed on the pile, to the placement of a final radon barrier, including periods of standby, and time periods prior to and during the placement of lixiviant on a heap leach pile. The commenters also took the position that heap leach piles that are drying out should be subject to a radon emission standard.

*Response:* The EPA acknowledges and appreciates the commenters' concurrence with the EPA's authority to regulate radionuclide emissions at holding or evaporation ponds at conventional mills, at ISL facilities and at heap leach facilities.

When the EPA initially promulgated Subpart W in 1986, we identified radon as the radionuclide released to air that presented the highest risk at uranium recovery facilities and determined that units managing uranium byproduct material or tailings were the most significant source of radon emissions (51 FR 34056). Since 1986 and re-promulgation in 1989, Subpart W has only regulated units that manage uranium byproduct material or tailings at uranium recovery facilities (40 CFR 61.250). Other potential emission points in these facilities were not previously the subject of Subpart W regulation and were not assessed for the 1989 rulemaking. The EPA's CAA section 112(q) review of Subpart W was limited to the existing standard. Because Subpart W did not regulate other potential emission points, the EPA did not include any other potential emission points in its CAA section 112(q) review. In this final rule, the EPA continues to regulate the management of uranium byproduct material or tailings from conventional mills, from ISL facilities and from heap leach piles.

With respect to regulation of heap leach piles, the EPA similarly retained the scope of Subpart W's applicability to sources that manage uranium byproduct material or tailings from heap leach operations. The EPA determined that, for purposes of Subpart W, while lixiviant is being sprayed on heap leach piles, the piles are part of the milling process rather than an impoundment whose function is to manage uranium byproduct material or tailings. The final rule does, however, cover the other impoundments used to manage the uranium byproduct material or tailings associated with the heap leaching operation and covers the heap leach pile during the period between the

conclusion of processing and the day that final closure begins. See Section IV.D.

*Comment:* Several commenters stated that the NRC has exclusive jurisdiction over the radiological and non-radiological aspects of uranium mill operations and the nuclear energy business and that the EPA lacks jurisdiction, particularly once the NRC promulgates conforming regulations. Commenters question the need to retain Subpart W at all, with one commenter contending that the existence of the Atomic Energy Act (AEA) makes Subpart W redundant and not necessary.

One commenter takes the position that the EPA does not have authority to define when uranium recovery facilities are considered to be "active" or involved in "operations." Instead, the commenter states that the NRC, not the EPA, has authority over decommissioning and decontamination of AEA-licensed source material recovery facilities, including the mill itself, site soil cleanup, final tailings stabilization, and groundwater restoration or corrective action. Further, the commenter states it is inefficient for uranium recovery operations to obtain two separate authorizations with essentially the same requirements for radon risk from fluid retention impoundments (*i.e.*, the NRC operating license or license amendment and the EPA Subpart W construction approval), and that these duplicative requirements are inconsistent with the EPA's past efforts towards regulatory efficiency evidenced by the rescissions of 40 CFR part 61, subparts I and T.

Another commenter states the Department of Energy also has authority to regulate this industry.

Alternatively, some commenters supported the EPA's authority under the CAA to regulate HAPs, particularly radon, from uranium processing and do not believe that the CAA limits the EPA's regulatory authority with respect to 11e.(2) byproduct material<sup>11</sup> at uranium recovery mill operations. Similarly, a commenter supported the proposed clarification to 40 CFR 61.252(b) (§ 61.252(a)(2) in the final rule) that the EPA, and not the NRC, is the regulatory agency administering the radon NESHAP requirements.

*Response:* The EPA disagrees that it lacks authority to regulate, under CAA section 112, the radionuclide air

<sup>11</sup> UMTRCA amended the AEA definition of "byproduct material" by adding a second category. Section 11e.(2) byproduct material is "the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content."

emissions of sources also regulated pursuant to the AEA by the NRC. The CAA lists radionuclides as a HAP under CAA section 112(b)(1), and section 112(q) explicitly retains standards such as Subpart W that were in effect before the date of enactment of the CAA Amendments of 1990. In addition, UMTRCA resolves this issue by quite explicitly stating that “[n]othing in this chapter applicable to byproduct material . . . shall affect the authority of the [EPA] under the Clean Air Act of 1970, as amended . . .” (42 U.S.C. 2022(e)). The legislative history is similar: “Authorities of the EPA under other laws would not be abridged by the new requirements” (H. Rep. No. 1480, 95th Cong., 2d Sess. 6, p. 21). There is no indication that Congress intended UMTRCA to preempt the EPA’s regulatory authority under the CAA; rather Congress expressly contemplated the EPA authority to simultaneously regulate under both legislative schemes (54 FR 51690–51691). Similarly, the EPA’s regulation of the uranium processing industry works in concert with the AEA and the NRC’s regulations.

*Comment:* Some commenters stated that the NRC, not the EPA, has exclusive authority over the definition of 11e.(2) byproduct material, as well as the material itself. Commenters question the EPA’s authority to promulgate a new definition for “11e.(2) byproduct material” or to equate the definition to the term “mill tailings.” The commenters opine that the EPA may not infringe on NRC authority by proposing an alternative definition of 11e.(2) byproduct material.

One commenter also thinks that the EPA does not have statutory authority to define tailings as restoration fluid because that authority rests exclusively with the NRC.

*Response:* The EPA disagrees with these comments. The EPA has authority to regulate radon emissions and this authority is not limited by the AEA or the NRC. Radionuclides, including radon, are listed HAPs in CAA section 112(b). The EPA regulated radon emissions from uranium byproduct material or tailings impoundments before the list of HAPs in CAA section 112(b) was added as part of the CAA Amendments of 1990 and CAA section 112(q) explicitly retains standards that were in effect before the 1990 CAA Amendments were enacted. The EPA’s regulation of the uranium processing industry works in concert with the NRC’s regulation. The EPA has authority to promulgate definitions under the CAA as it deems appropriate and is not limited to the AEA’s

definition of “byproduct material” or “tailings,” or the NRC’s definition in 10 CFR 40.4. The EPA first defined “uranium byproduct material or tailings” when promulgating Subpart W in 1986 (51 FR 34066, September 24, 1986). The EPA’s definition identifies the scope of material covered by the Subpart W regulations and does not preempt the NRC’s AEA authority. The definition in Subpart W of uranium byproduct material or tailings is not substantially or meaningfully different from the NRC’s definition of byproduct material in 10 CFR 40.4 or the definition of 11e.(2) byproduct material and should not result in conflict. See also Section IV.F.2.

Regarding the question of restoration fluids, we note that the designation of restoration fluids as “waste produced by the extraction or concentration of uranium from any ore processed primarily for its source material content” is consistent with the approach taken by the NRC. See Staff Requirements Memorandum—SECY–99–013, “Recommendation on Ways to Improve the Efficiency of NRC Regulation at *In Situ* Leach Uranium Recovery Facilities,” July 26, 2000.

*Comment:* One commenter opposed comments of the regulated industry which argued that the EPA does not have authority to directly regulate radon emissions from uranium processing facilities. The commenter argued that the industry’s arguments amount to an argument the EPA lacks authority over emissions from uranium mill tailings impoundments. The commenter opined that if industry wishes to remove a tailings facility from NESHAP regulation, it should submit a petition showing that radon emissions are not hazardous, but believes that such an effort would fail. The commenter continued that the EPA’s proposed rule continues to recognize the health hazards of uncontrolled radon emissions from uranium mill tailings and the rulemaking record confirms that CAA NESHAP regulation is a necessary part of the EPA’s role in regulating uranium mill tailings pursuant to its CAA and UMTRCA authorities.

Numerous commenters supported the EPA’s decision to regulate radon emissions from uranium mill facilities. Specifically, two commenters state that the EPA has authority to regulate all radon at mills and another commenter confirmed that the EPA has a role in regulating uranium mill tailings. A third commenter stated that the EPA has authority to conduct radon flux measurements.

*Response:* The EPA acknowledges and appreciates these comments. The EPA

agrees that it has authority under the CAA to regulate radionuclide emissions from uranium byproduct material or tailings as radionuclides, including radon, are listed HAPs in CAA section 112(b)(1). Data confirm conclusively that radon-222 emissions, ambient concentrations, bioaccumulation or deposition of radon and its decay products cause adverse effects on public health and the environment.

#### *B. Retaining the Radon Flux Requirement for Impoundments in Existence on December 15, 1989*

1. How did we address the radon flux requirement in the proposed and final rules?

After reviewing stakeholder comments and verifying the information provided in them, we are not eliminating the radon flux standard of 20 pCi/m<sup>2</sup>-sec for all impoundments in existence prior to or on December 15, 1989. In the proposed rule, we provided information to show that the impoundments in existence prior to December 15, 1989 met the management practice requirements of impoundments constructed after that date (79 FR 25394). Since the conventional impoundments in existence prior to or on December 15, 1989 appeared to meet those management practice standards, we proposed that all conventional impoundments would be subject to the same management practices, regardless of the date of construction. We also proposed that all conventional impoundments (including those in existence prior to or on December 15, 1989) must meet the requirements of one of the two management practice standards, and that the flux standard of 20 pCi/m<sup>2</sup>-sec would no longer be required for any impoundments.

During the comment period we received information that led us to conclude that we had erred in stating an equivalency between the two types of impoundments. We originally stated that the Sweetwater and Shootaring impoundments had a double liner system equivalent to the impoundments designed after December 15, 1989. We were incorrect. Commenters<sup>12</sup> showed that the liner systems at these two facilities were not double liners. Additionally, we were originally informed that Cell 3 at the White Mesa facility would be closed by 2014. In fact,

<sup>12</sup> EPA–HQ–OAR–2008–0218–0151, –0153, –0155, –0162. To be clear, our error was in believing that these impoundments were constructed in a manner that allowed them to meet the more stringent standards that were put in place after they were constructed. The standards applicable to these impoundments at the time of the 1989 rulemaking did not require double liners.

it has not.<sup>13</sup> After reviewing the information obtained during the public comment period, we concluded that these impoundments do not meet the management practice standards we proposed for impoundments constructed after 1989. Our analysis also showed that the impoundments in existence on December 15, 1989 can monitor radon emissions to determine compliance with the existing 20 pCi/m<sup>2</sup>-sec standard. It is a generally available management practice standard that successfully limits radon emissions from these area sources, as provided for in CAA section 112(d)(5). Therefore, we decided to retain the radon flux standard (20 pCi/m<sup>2</sup>-sec) and monitoring requirement for conventional impoundments in existence on or before December 15, 1989 as the applicable GACT-based management practice. Because the 1989 rule required these impoundments to comply with the requirements at 40 CFR 192.32(a)(1), we concluded that such a management practice is generally available and contributes to the control of radon emissions as described more fully in Section IV.A.2.

Some commenters also supported requiring compliance with the flux standard for all impoundments, including those not now subject to it, but we have concluded that to be unnecessary if the owner/operator of an impoundment follows the design and other management practices outlined in the GACT-based standard because these measures are expected to effectively control total radon emissions.

## 2. What did our updated risk assessment tell us?

As described in the preamble to the proposed rule, we updated the risk analysis we performed when we promulgated Subpart W in 1989 (79 FR 25395, May 2, 2014). We performed a comparison between the 1989 risk assessment and current risk assessment approaches, focusing on the adequacy and the appropriateness of the original assessments.<sup>14</sup>

Because we proposed to establish GACT-based standards to limit radon emissions from the management of uranium byproduct material or tailings at uranium recovery facilities, thereby eliminating any emissions standards and monitoring requirements, it was not necessary for us to update the risk assessment. GACT is not determined on the basis of risk. We conducted the

analysis to inform ourselves regarding the continued protectiveness of the radon flux standard as we considered whether the proposed GACT approach could be extended to impoundments in existence on December 15, 1989. We concluded that, even using updated risk analysis procedures (*i.e.*, using procedures updated from those used in the 1980s), the existing radon flux standard appears to be protective of the public health and the environment.

The updated risk assessment involved evaluating exposures to off-site (maximally exposed) individuals and populations from reported total site radon emissions at a number of uranium recovery facilities. In doing so, we found that the risks to individuals and populations were comparable to or lower than those estimated in the 1989 rulemaking. The updated risk assessment employed the most recent risk factors for radon inhalation, which are age-averaged to incorporate the sensitivity of children to radiation. The factors used in the 1989 risk assessment were based on exposures to adults.

This final rule retains the flux standard for conventional impoundments in existence on December 15, 1989. The updated risk assessment and our conclusion that the radon flux standard continues to be protective support our decision to retain the flux standard in the rule. The updated risk assessment is included in the Background Information Document (BID) for the final rule.

In developing the risk assessment and BID, we also conducted environmental justice analyses for the immediate areas (*i.e.*, counties) surrounding the existing and proposed uranium recovery facilities. For all of the sites considered together, the data did not reveal a disproportionately high incidence of minority populations being located near uranium recovery facilities. However, certain individual sites may be located in areas with high minority populations. Those sites would need to be evaluated during their individual licensing processes. The data also did not reveal disproportionately high incidence of low-income populations being located near uranium recovery facilities. We also considered environmental justice analyses that were performed during the EPA's review of construction applications under 40 CFR 61.08. These analyses were conducted by EPA Region 8 in connection with the Piñon Ridge Uranium Mill in Colorado and the Lost Creek ISL uranium project in Wyoming.

## 3. What key comments did we receive on the radon flux requirement?

We received comments stating that the monitoring requirements for impoundments in existence on December 15, 1989 should be retained and that our proposal was based on faulty information. We also received comments recommending that monitoring be extended to all impoundments. Some commenters supported lowering the flux standard.

*Comment:* Many commenters opposed the proposed elimination of the monitoring requirement for conventional impoundments in existence on December 15, 1989. Commenters expressed a general concern that no data would be available, but several also specifically questioned our rationale for doing so. They provided information indicating that the three "existing" (*i.e.*, pre-1989) impoundments would not be able to meet the work practice standards (now designated as GACT). By contrast, a few commenters supported eliminating the monitoring requirement based on the effectiveness of the management practices.

*Response:* We are retaining both the radon flux standard and the monitoring requirement for conventional impoundments in existence on December 15, 1989. Commenters provided information demonstrating that the conventional impoundments previously required to monitor radon emissions (*i.e.*, Cell 3 at the White Mesa Mill and the impoundments at Shootaring Canyon and Sweetwater) are unable to meet the GACT-based standards. Although we agree with the other commenters that the GACT-based standards are effective in limiting radon emissions, they were predicated on the impoundments meeting certain minimum requirements. Because comments included information demonstrating some conventional impoundments in existence on December 15, 1989 do not meet these minimum requirements or did not enter closure as the EPA expected, it is necessary and appropriate to retain the radon flux standard and monitoring requirement for these units.

*Comment:* A number of commenters expressed the view that monitoring should not be limited to conventional impoundments constructed before December 15, 1989. They asserted that they have little confidence that the management practices in place for newer impoundments are effectively being implemented, and argue that it is not possible to verify their effectiveness without monitoring. The commenters

<sup>13</sup> EPA-HQ-OAR-2008-0218-0151, -0170.

<sup>14</sup> "Risk Assessment Revision for 40 CFR part 61 Subpart W: Task 4—Detailed Risk Estimates," prepared by S. Cohen & Associates, November 2011, Docket No. EPA-HQ-OAR-2008-0218-0078.

also expressed concern that impoundments that are drying out (“dewatering”) are emitting larger amounts of radon, and that without monitoring the operators are not compelled to provide additional soil cover.

*Response:* The EPA reviewed the management practices prescribed for conventional impoundments constructed after December 15, 1989 and reaffirmed its determination that they effectively reduce radon emissions. The radon flux standard and monitoring requirement were instituted in the 1989 rulemaking to provide a means to control radon emissions from impoundments that were constructed and operated according to earlier industry practices. The EPA found that the management practices would represent a demonstrable improvement compared to those industry practices. The Agency has concluded that the appropriate action to satisfy its CAA review is to establish these management practices as GACT-based standards. We agree that operators need to take appropriate action to control radon during the period when the impoundment is operating, and not allow excessive drying during standby or other periods of limited activity. The management practices are intended to limit radon emissions. For conventional impoundments and heap leach piles, the management practices limit the exposed area and/or number of impoundments at a uranium recovery facility, which effectively limits the opportunity for radon emissions. For non-conventional impoundments, ensuring that the material is saturated will limit radon emissions by approximately 95% compared to dry materials.

*Comment:* Some commenters favored retaining the emissions standard for conventional impoundments constructed before December 15, 1989, but at a more stringent level. One commenter stated that a standard below 10 pCi/m<sup>2</sup>-sec would be appropriate, and also that a review of current control technologies would support a standard of 1 to 5 pCi/m<sup>2</sup>-sec. Another commenter noted that the 1989 Background Information Document found that a 6 pCi/m<sup>2</sup>-sec standard was achievable and cost effective. This general view was supported by other commenters, with one stating that the 20 pCi/m<sup>2</sup>-sec standard was established “for economic reasons.” One commenter also expressed concern that the EPA did not evaluate monitoring methods other than Method 115, and specifically referred to the Landauer RadTrak.

*Response:* Because the proposal involved eliminating all monitoring, the EPA did not evaluate the impacts of implementing other standards or monitoring methods. However, we did reaffirm that the 20 pCi/m<sup>2</sup>-sec standard remains protective, and we also find that Method 115 remains an appropriate method to measure radon emissions from conventional impoundments.<sup>15</sup> We disagree with the characterization of the 20 pCi/m<sup>2</sup>-sec flux standard as based on economics. As stated in the preamble to the 1989 final rule, when determining an ample margin of safety for the rule, “As explained above, the risks from current emissions are very low. A NESHAP requiring that emissions from operating mill tailings piles limit their emissions to no more than 20 pCi/m<sup>2</sup>-sec represents current emissions. EPA has determined that the risks are low enough that it is unnecessary to reduce the already low risks from the tailings piles further” (54 FR 51680, December 15, 1989). The update of the 1989 risk assessment conducted for this rulemaking confirms that the risk to public health from uranium byproduct material or tailings managed at operating uranium recovery facilities is comparable to, if not lower than, the level of risk considered presumptively acceptable in the 1989 rulemaking. See Section IV.B.2.

### C. GACT for Conventional Impoundments Constructed After December 15, 1989

1. How did we address conventional impoundments constructed after December 15, 1989 in the proposed and final rules?

We proposed to designate the management practices promulgated in the 1989 rulemaking for impoundments constructed after December 15, 1989 as GACT-based standards for all conventional impoundments. In doing so, we evaluated the reasoning used in the 1986 and 1989 Subpart W rulemakings to determine that the phased disposal and continuous disposal management practices protect public health with an ample margin of safety (54 FR 51681).

We initially defined these two management practices because they provided a means for newly-designed impoundments to limit radon emissions, either by limiting the overall size of the impoundment or by limiting the area of dried (dewatered) uranium byproduct material or tailings that can

be exposed at any time. We found the two management practices to improve performance (risk to exposed individuals and population) by approximately 35% to more than 50%, respectively, compared to earlier practices of constructing larger impoundments without limiting their number or the exposed area. The potential for larger impoundments or many smaller impoundments to remain uncovered and their radon emissions uncontrolled if bankruptcy prevented proper closure was considered to provide a further advantage to the two management practices (54 FR 51680).

Owners and operators of uranium recovery facilities in the United States have all used the phased disposal method for management of uranium byproduct material or tailings in conventional impoundments, making it a generally available management practice to control radon emissions. We have found no reason to believe that this method is unworkable, unreasonably burdensome or ineffective in limiting radon emissions. Keeping the uranium byproduct material or tailings wet or partially covered, as is typical practice, further reduces radon emissions. These industry practices also clearly demonstrate that the phased disposal method is a generally available technology. In addition, while there has been no use of the continuous disposal method in the United States, it has been successfully employed in other countries, and was proposed for use by some U.S. companies in the 1980s. Therefore, this final rule designates the phased disposal and continuous disposal methods as elements of GACT-based standards for conventional impoundments constructed after December 15, 1989. Because these impoundments are separately required to comply with the requirements at 40 CFR 192.32(a)(1), we concluded that such a management practice is generally available and contributes to the control of radon emissions as described more fully in Section IV.A.2. Conventional impoundments must also comply with the construction requirements in 40 CFR 192.32(a)(1).

2. What key comments did we receive on conventional impoundments constructed after December 15, 1989?

We received some comments questioning the effectiveness of the 1989 management practices and our decision to adopt those practices as GACT-based standards. These commenters argued that there is no basis for concluding that these practices are effective in limiting radon emissions when no confirmatory monitoring has been done. They further

<sup>15</sup> “Report on the Review of Method 115 to Monitor Radon Emissions From Uranium Tailings,” prepared by S. Cohen & Associates, September 2008, Docket No. EPA-HQ-OAR-2008-0218-0122.

assert that the work practices were inadequate because practices that are actually effective in reducing radon emissions, such as maintaining a soil or water cover, were not elements of the 1989 work practices or the proposed GACT management practices.

*Comment:* Several commenters believe our GACT standards are unsupported because there is no monitoring data to demonstrate the effectiveness of the measures for post-1989 impoundments. Commenters criticize the analysis of control technologies in the BID prepared to support the proposal as flawed and insufficient. One commenter states that limiting the size of the impoundment is not in itself an effective means to limit radon emissions without monitoring, reporting, and the requirement of liquid or soil application. This and another commenter also believe that any new impoundments should be required to use the continuous disposal method, as the commenters view the phased disposal method as ineffective in controlling radon emissions, particularly when using water cover. The first commenter further disputes the reliance on 40 CFR 192.32(a)(1) as an effective control technology to limit radon emissions. Another commenter also suggests that the most effective control technology is an emissions limit coupled with monitoring, and believes the rule should be re-crafted along those lines.

Commenters also asserted that we have not sufficiently examined other technologies employed either in other countries or in related industries. One commenter argues that other technologies (e.g., dry-stack placement, paste tailings, solidification) may be superior to open-air storage and cover in conventional impoundments, but were not evaluated in the BID.

*Response:* Our review under CAA section 112(q)(1) focused on the management practices applicable to post-1989 conventional impoundments (i.e., continuous or phased disposal). However, as noted in the proposal, we also considered control technologies employed at other facilities in the same industrial sector and internationally. We found that the continuous and phased disposal methods adequately control radon emissions and meet the requirements for GACT—these management practices are generally available and effectively prevent adverse health impacts from radon emissions. We recognize the commenter's position that the design and engineering requirement in 40 CFR 192.32(a)(1) does not directly limit radon emissions. However, the design

requirement serves two purposes. Retaining moisture or maintaining liquid levels within the impoundment does effectively inhibit radon flux while at the same time preventing releases to ground water. It is possible and important to achieve both goals.

Regarding the area limitation, we disagree with the commenters. The focus of the 1989 analysis was on limiting the surface area from which radon would be emitted.<sup>16</sup> Surface area is directly correlated with radon emanation—the smaller the surface, the lower the overall emissions, given similar materials. While the 1989 rulemaking clearly recognized that the use of soil cover or water are also effective in reducing radon emissions and were commonly employed by industry, the acceptability of the promulgated work practices was not predicated on those additional measures being employed, except to the extent that it was necessary to limit the exposed area when using the continuous disposal method.

*Comment:* Some commenters stated that the designation as an area source is not in itself sufficient to justify use of GACT. Commenters cite the legacy of contamination associated with the uranium industry as justifying the “strongest preventive measures.” Similarly, other commenters accuse the industry of “cutting corners” and believe GACT “runs counter to everything EPA knows” about past practices. Another commenter argues that the Agency’s “discretion” must be supported by full and complete explanation and justification. These and other commenters also believe the EPA has not sufficiently considered MACT approaches.

*Response:* When setting standards, the EPA aims to ensure that the promulgated standards effectively protect against adverse environmental and health impacts, regardless of whether such standards are based on GACT or MACT. For area sources, the Administrator has the discretion under CAA section 112(d)(5) to set standards based on GACT in lieu of setting MACT standards under sections 112(d)(2) and (d)(3), which is required for major sources. See Section IV.A.2 for discussion of regulating these units as area sources. Under CAA section 112(d)(5), the Administrator may elect to promulgate standards or requirements for area sources “which provide for the use of generally available control

<sup>16</sup> “Either one of these technologies will ensure that future risks will be kept under control by assuring that *only small amounts of tailings are uncovered at any time*” (54 FR 51681 (emphasis added)).

technologies or management practices by such sources to reduce emissions of hazardous air pollutants.” Consistent with section 112(d)(5), we are revising Subpart W to reflect GACT-based standards. Based on the EPA’s evaluation of available information, the GACT-based approach in the final rule provides the necessary protections from management of uranium byproduct material or tailings. The emission standards and management practices established in Subpart W will appropriately reduce radon emissions from uranium recovery facilities.

#### D. GACT for Heap Leach Piles

1. How did we address heap leach piles in the proposed and final rules?

a. When are heap leach piles regulated under Subpart W?

We proposed to regulate the heap leach pile from the moment that uranium begins leaching from the ore pile. This approach was based on the view that uranium byproduct material or tailings is produced the moment the lixiviant passes through on its first pass and uranium begins to be leached from the ore (79 FR 25403). At the point of uranium movement out of the heap, what remains is uranium byproduct material or tailings as defined by 40 CFR 61.251(g). In other words, what remains in the heap is the waste produced by the extraction or concentration of uranium from ore processed primarily for its source material content. The heap leach pile manages that uranium byproduct material or tailings, even as the pile is further leached to extract uranium. The proposal placed the emphasis on the presence of uranium byproduct material or tailings in the heap leach pile.

We also requested comment on an alternative approach we described in the proposal (79 FR 25398). Under this approach, heap leach piles would not fall under Subpart W until after leaching is permanently discontinued. This approach is based on the view that, as long as the heap is being leached, the ore on the heap leach pad is being processed. While uranium byproduct material or tailings may *exist* in the heap, the heap does not become engaged in managing uranium byproduct material or tailings until leaching is permanently discontinued. This view places the emphasis on the continued extraction of uranium from the heap leach pile. Only after that extraction potential is exhausted, and only uranium byproduct material or tailings remains, would the pile fall under Subpart W.

Many commenters (primarily those from industry) supported basing the

final rule on this alternative view. These commenters argued that the heap leaching cycle is essentially serving the same function as the successive leaching of uranium that occurs in the leach and counter current decantation circuits of a conventional mill, where the ore pulp is successively leached in a series of leach tanks and thickeners. The material does not become uranium byproduct material or tailings (*i.e.*, waste) and fall under the requirements of Subpart W until it leaves the final thickener and is discharged to the tailings impoundment.

Although we proposed to bring the heap under the jurisdiction of Subpart W based upon the presence of uranium byproduct material or tailings within the pile, after further consideration we find the commenters' reasoning compelling and more consistent with previous application of the rule. Subpart W has historically not regulated radon emissions from the milling or extraction process, even at the intermediate points where residuals from uranium extraction make up the bulk of the material being processed, which may be the situation as processing of the heap progresses. Subpart W has regulated only the disposition of the wastes at the end of the separations process. Consistent with this precedent, the heap leach pile is like a conventional impoundment and will be subject to Subpart W once uranium extraction is complete and only uranium byproduct material or tailings remains. Until that time, the heap is considered to be either an unprocessed ore pile or a uranium recovery facility. Thus, heap leach piles are regulated by Subpart W only during the period between the end of processing (*i.e.*, after the pile's operational life) and the beginning of closure. As described in Section IV.F.1.a, and consistent with the requirements applicable to conventional and non-conventional impoundments, the final rule requires that operators provide written notification to the EPA and the NRC that the heap leach pile is being managed under an approved reclamation plan for that pile or the facility closure plan. Impoundments used to manage liquids resulting from the heap leach operation, to the extent they contain uranium byproduct material or tailings, are considered non-conventional impoundments subject to Subpart W, as defined in today's final rule.

There is a significant aspect of heap leach pile management that is important to these regulations. Several commenters from industry stated that a heap leach pile, unlike a conventional impoundment, will immediately begin

closure after processing has concluded (either closure in place, or possibly removal for placement in a conventional tailings impoundment). If that is the case, there will be no period when the heap is subject to the requirements of Subpart W. Because there are no heap leach facilities operating in the United States, we have no basis for disputing these statements of industry's intent. Nevertheless, we have concerns that these good intentions may prove insufficient to ensure that closure takes place as expeditiously as the commenters believe. There is some potential that heap leach piles will complete processing but not immediately enter closure. During such a period the owner or operator is only using the pile to manage uranium byproduct material or tailings, and the heap leach pile is then subject to the requirements of Subpart W. The specification in the final rule that final closure does not begin until the operator has provided a written notification to the EPA and the NRC will minimize the potential for confusion regarding the applicability of Subpart W. A further concern might be that operators continue "processing" the pile indefinitely, thereby postponing the costs associated with closure. This would be a matter for the NRC or NRC Agreement States to consider.

We recognize that heap leach piles will emit radon while they are being processed. However, as explained above, Subpart W has traditionally been applied to uranium byproduct material or tailings after exiting the extraction process. Thus, Subpart W has not been applied to other sources of radon at uranium recovery facilities where wastes are present, such as material in thickeners or other processing units. The NRC, or NRC Agreement State, regulates the radionuclide emissions from all sources at a uranium recovery facility. The operator is required to report particulate radionuclide and Rn-222 concentrations at the facility boundary. Thus, radon emissions from sources not covered under Subpart W, including those from the raw ore in heap leach piles or processed yellowcake, are captured by the NRC reporting requirements. However, we emphasize that the best way to control radon emissions from heap leach piles after they have completed processing is to expeditiously close them and install a permanent radon barrier.

#### b. Phased Disposal

As described in the preceding section, after reviewing comments, we have decided to require that heap leach piles conform to the standards for other

uranium recovery facility impoundments only during the period between processing (*i.e.*, after the pile's operational life) and closure. Heap leach piles meeting this description will conform to the GACT-based standard of phased disposal (piles that are 40 acres or less in area, and no more than two in this status at any time) and follow the construction requirements of 40 CFR 192.32(a)(1). We note that piles that will close in place would separately be required by NRC or Agreement State license to meet the construction requirements.

Since heap leach piles are in many ways similar to the design of conventional impoundments, the same combination of phased disposal management practices (limitation to no more than two heap leach piles that are no longer being processed but have not yet entered closure, each one no more than 40 acres in area) that limit radon emissions from conventional impoundments will also limit radon emissions from heap leach piles. Because this management practice is generally available for conventional impoundments, heap leach piles can control radon emissions through the same practice. We determined that phased disposal is a GACT-based management practice that will effectively limit radon emissions from these units. Use of the phased disposal management practice will limit the amount of exposed uranium byproduct material or tailings that can emit radon. Because these units will be separately required to comply with the requirements at 40 CFR 192.32(a)(1), we concluded that such a management practice is generally available and contributes to the control of radon emissions as described more fully in Section IV.A.2.

#### c. Regulating the Moisture Content of Heap Leach Piles

The third issue we are addressing is the proposed requirement for heap leach piles to maintain a 30% moisture content. In the proposal we recognized that owners and operators of conventional impoundments also limit the amount of radon emitted by keeping the uranium byproduct material or tailings in the impoundments covered, either with soil or liquids (79 FR 25398). At the same time, we recognized that keeping the uranium byproduct material or tailings in the heap in a saturated or near-saturated state (in order to reduce radon emissions) is not a similarly practical solution. In the definitions at 40 CFR 61.251(c) we have defined "dewatered" tailings as those where the water content of the tailings does not

exceed 30% by weight. We proposed to require operating heaps to maintain moisture content of greater than 30% so that the uranium byproduct material or tailings in the heap is not allowed to become dewatered, which would allow more radon emissions. We specifically asked for comment on the amount of liquid that should be required in the heap, and whether the 30% figure was a realistic objective.

After considering stakeholder comments and information, we conclude that it is physically impossible to maintain a 30% moisture content within the heap leach pile and have it remain stable.<sup>17</sup> Calculations submitted by numerous commenters showed that maintaining a 30% moisture content across the heap leach pile would require the pile to be almost submerged. Further, such a condition would place a great amount of hydraulic head on the liner system, potentially causing failure. So, the final rule does not include the requirement to maintain 30% moisture content, even for the period between the end of processing and the beginning of closure, when the pile will be allowed to “dry” in preparation for placing a permanent radon barrier. We do encourage the NRC and facility operators to consider the appropriate use of soil and liquid to limit radon emissions from heap leach piles, as well as methods to reduce the potential for wind erosion (*e.g.*, by spraying or covering the pile when not actively being leached). However, we emphasize that the best way to control radon emissions from heap leach piles after they have completed processing is to expeditiously close them and install a permanent radon barrier.

## 2. What key comments did we receive on heap leach piles?

Comments submitted on heap leach piles focused on the proposed approach to regulation and the proposed requirement to maintain a 30% moisture content.

*Comment:* Most commenters on this topic disagreed with our proposal to regulate heap leach piles under Subpart W while they are being processed. These commenters expressed the view that material in the heap leach pile does not become uranium byproduct material or tailings until processing is complete, including a final rinse. As stated by one commenter, “Heap leaching is part of the milling process, and the proposed rules would interfere with such processing operations.” The commenter believes that, in essence, the heap leach

pile is analogous to the conventional mill, which we have not previously proposed to regulate under Subpart W.

Further, several of these commenters stated that heap leach piles will immediately enter into closure upon the cessation of processing, so there is no period when they are “operating” simply as uranium byproduct material or tailings management units. As a result, they see no time at which Subpart W can apply to heap leach piles.

Some commenters raised the distinction between “close in place” piles and “on-off” piles. Commenters explain that the latter operations involve the removal of the processed heap and placement in a conventional impoundment. In this case, the commenters agree that the uranium byproduct material or tailings from the heap, and the impoundment into which it is placed, would be subject to Subpart W.

*Response:* The final rule does not include requirements related to heap leach piles undergoing processing. We acknowledge the comments that indicate that uranium byproduct material or tailings is generated once processing begins. To ensure that heap leach piles are regulated consistent with other units subject to Subpart W, we conclude that the heap leach pile is, for purposes of Subpart W, more appropriately considered part of the milling process than as an impoundment whose function is to manage uranium byproduct material or tailings. In other words, while the pile may *contain* uranium byproduct material or tailings, the pile itself *is* the ore from which uranium is being extracted, and does not become a waste until that process is completed. The rule does, however, cover the other impoundments used to manage the uranium byproduct material or tailings associated with the heap leaching operation.

We appreciate the commenter’s description of the “on-off” heap leach piles and agree that if a processed heap is removed and placed in a conventional impoundment, that impoundment is subject to Subpart W.

We emphasize the importance of closing piles “as expeditiously as practicable considering technological feasibility” once processing concludes. Industry commenters provided assurances that there would be no untoward delay in beginning the closure process. We encourage NRC to ensure that this is the case. Closure is a more comprehensive system to assure that emissions are minimized for the long term. Once processing has ended, the

heap leach pile serves only as a uranium byproduct material or tailings management structure. Such a pile will be subject to Subpart W if the operator has not informed regulators that it is being managed under an approved reclamation plan. As set forth in the final rule, in such a situation, the phased disposal restrictions will apply (no more than two such piles at any time, with area no greater than 40 acres each). Heap leach piles subject to Subpart W must also comply with the construction requirements at 40 CFR 192.32(a)(1). Timely closure of heap leach piles will be better for public health than maintaining piles in an interim state in which they fall under Subpart W.

*Comment:* Some comments supported our proposed approach, and recommended that we establish an emissions standard and monitoring requirements for heap leach piles. These commenters agree that, because uranium byproduct material or tailings is generated within the heap leach pile at the time processing begins, the pile serves to manage that material during the operation of the facility. These commenters believe this function brings it under the scope of Subpart W. These commenters also take a more expansive view, and believe the EPA is obligated under the CAA to address the entire process at heap leach facilities in the final rule. In this approach, Subpart W would apply to ore stockpiles, ore crushing and heaps that are awaiting processing, as well as to the heap until placement of the final cover. One commenter further recommends that open-air heap leaching not be approved, when leaching can be conducted more safely and with lower emissions inside a designed enclosure.

*Response:* As stated in the response to the previous comment, Subpart W will not regulate heap leach piles while they are being processed (*i.e.*, during the heap leach pile’s operational life). We proposed to apply certain management practices to heap leach piles, but did not propose to establish a radon emission standard and monitoring requirements. Regarding the extension of Subpart W to ores and other similar materials, when the EPA initially promulgated Subpart W in 1986, we identified radon as the radionuclide released to air that presented the highest risk at uranium recovery facilities and determined that units managing uranium byproduct material or tailings were the most significant source of radon emissions (51 FR 34056). Since 1986 and re-promulgation in 1989, Subpart W has only regulated units that manage uranium byproduct material or tailings

<sup>17</sup> EPA-HQ-OAR-2008-0218-0144, -0162, -0169, -0170.



at uranium recovery facilities. 40 CFR 61.250. Other potential emission points in these facilities were not previously the subject of Subpart W regulation and were not assessed for the 1989 rulemaking. The EPA's CAA section 112(q) review of Subpart W was limited to the existing standard. Because Subpart W did not regulate other potential emission points, the EPA did not include any other potential emission points in its CAA section 112(q) review. In this final rule, the EPA continues to regulate the management of uranium byproduct material or tailings from conventional mills, from in situ leach facilities and from heap leach piles.

*Comment:* A significant number of commenters raised objections to the proposed requirement that heap leach piles be maintained at 30% moisture content as a means to limit radon emissions. Calculations submitted by numerous commenters have shown that to maintain a 30% moisture content across the heap leach pile would require the pile to be almost submerged. The commenters broadly agreed that this is an unrealistic goal that could severely undermine the stability of the pile. Further, it would result in a significantly greater hydraulic head, which raises the risk of liner failure. Several commenters also consider the monitoring requirement to be difficult to implement. As with the proposal to maintain one meter of liquid in non-conventional impoundments, concern was also expressed regarding the source of the water. Commenters suggested that a simpler water balance, which would involve calculations of the amount of liquid entering and leaving the pile, would be a more implementable method of estimating moisture content.

*Response:* Recognizing the difficulties associated with maintaining a 30% moisture content across the heap leach pile, the final rule does not include a requirement related to the moisture content of heap leach piles. That being said, keeping the pile wet or covered will help reduce radon emissions. We encourage operators as well as the NRC and NRC Agreement States to consider methods that can be applied during the operational life of the heap leach pile.

#### *E. GACT for Non-Conventional Impoundments*

1. How did we address non-conventional impoundments in the proposed and final rules?

The purpose of non-conventional impoundments, also known as evaporation or holding ponds, is to manage liquids generated during and after uranium processing operations. We

proposed to require one meter of liquid to remain in the impoundment at all times (79 FR 25411). The liquid cover was proposed as a management practice that would limit radon emissions from the uranium byproduct material or tailings.

The Subpart W regulation as promulgated in 1989 did not clearly distinguish between conventional tailings impoundments and those operating as ponds (*i.e.*, those defined as "non-conventional impoundments" in this final rule). The proposed regulation intended to clarify this distinction.

For non-conventional impoundments, the proposed rule allowed for an unlimited number of units to be operating, with no size limitation, but required that a depth of one meter of liquid be kept above any precipitated solids (uranium byproduct material or tailings). The use of the word "liquid" is important here. Typically, operators divert process water to evaporation or holding ponds, where it may be recycled, treated, evaporated, or disposed by injection. Thus, it is likely that the liquid entering the impoundment will contain uranium byproduct material or tailings in solution or suspension. Some portion of this uranium byproduct material or tailings will settle out into sediments. In our proposal we did not specify that the one meter of liquid covering a non-conventional impoundment be fresh water; however, we did refer to "water" in the preamble, and the comments demonstrate that there has been some confusion about this point.

Various commenters described the cost of locating fresh water in the semi-arid and arid western portions of the United States in order to meet the one meter requirement. Other comments focused on the limitations in operational flexibility that a fresh water cover would create by changing the chemistry of a stream that is often recycled back into the extraction process, or noted that this requirement would require re-design of impoundments.

We recognize that this requirement could result in the need to use large volumes of water that may not be readily available in the arid to semi-arid areas in which most uranium recovery facilities operate. Even for facilities that maintain large volumes of process water in ponds, there would likely be some demand for fresh water as a supplement to maintain the required liquid level. Further, maintaining this level of liquid cover would result in placing significantly more hydraulic head on the liner systems for the impoundments, which is counter to existing state and

federal regulations and guidelines for operating these systems, as well as a concern to the Agency that the liner would be more susceptible to failure.

In light of these comments, we took a closer look at the proposed requirement. The best indicator of potential Rn-222 emissions during the impoundment's operating period is the concentration of Ra-226 in the liquid and sediment. The BID to support the 1989 rulemaking indicates that the Ra-226 concentrations in conventional uranium byproduct material or tailings is as much as an order of magnitude higher than evaporation pond sediments at the same uranium recovery facility (1989 BID Volume 2, Risk Assessments, EPA/520/1-89-006-1, Table 9-2, Docket No. EPA-HQ-OAR-2008-0218). We have recognized that keeping uranium byproduct material or tailings in conventional impoundments wet helps to limit radon emissions. Moreover, this management practice is used throughout the industry, even in arid regions, and can thus be considered "generally available." We have further recognized that the difference between uranium byproduct material or tailings that are saturated and those covered with one meter of liquid is negligible (79 FR 25398). Therefore, the final rule's requirement that solids remain saturated achieves the same goal as the proposed standard of maintaining a one-meter liquid cover.

Commenters also expressed concern over Rn-222 emissions resulting from Ra-226 dissolved in the liquid present in non-conventional impoundments, as opposed to solid materials in the bottom of the impoundment. A number of commenters questioned our conclusion that radon emissions from uranium byproduct material or tailings in non-conventional impoundments could be greatly reduced by keeping the solids saturated, and reduced to nearly zero by maintaining a liquid cover. The BID shows in Figure 12 that 100% saturated soil reduces radon emanation by nearly 95% compared to dry material, while one meter of liquid provides a further reduction of about 93%, or an overall reduction of greater than 99% (BID Equation 5.1).<sup>18</sup> In either case, radon emissions from non-conventional impoundments would be controlled to levels that represent limited risk to public health. However, commenters argued that actual data on the liquid contents of non-conventional impoundments (primarily from the

<sup>18</sup> See also "Risk Assessment Revision for 40 CFR part 61 Subpart W: Task 5—Radon Emissions from Evaporation Ponds," S. Cohen & Associates, November 2010, Docket No. EPA-HQ-OAR-2008-0218-0123.

White Mesa mill), when evaluated using a correlation in the updated risk assessment, showed radon emissions well in excess of 20 pCi/m<sup>2</sup>-sec.

We carefully evaluated the data and emissions analyses submitted by commenters. We determined that the data cited by the commenters did not support their conclusions. We conclude that our analysis in the proposal was correct regarding the characteristics of non-conventional impoundments and the radon attenuation that could be achieved. See Section IV.E.2 for more detail on this issue.

To summarize, we received comments that raise concerns regarding the economic and technical feasibility, as well as the practical effect, of specifying a liquid level for non-conventional impoundments. We further confirmed that keeping the sediments in a non-conventional impoundment at 100% saturation is nearly as effective as maintaining one meter of water (liquid) cover (Figure 12 in the BID for the final rule). The cost and logistics of maintaining a one-meter liquid cover in arid regions also favor maintaining saturation, especially given that saturation effectively controls emissions and will limit economic impacts.

We evaluated management practices in use at non-conventional impoundments in the industry that could achieve the goal of limiting radon-222 emissions from these units. These units are designed to hold liquid, and typically any uranium byproduct material or tailings contained in these impoundments is covered by liquid. Maintaining a liquid cover over the uranium byproduct material or tailings would effectively control radon and is a practice that is generally available to owners and operators of non-conventional impoundments. Therefore, we have revised the proposed rule language to indicate that the solids in a non-conventional impoundment must remain saturated at all times. In this final rule, we are establishing this condition, along with the liner requirements in 40 CFR 192.32(a)(1), as GACT-based standards for non-conventional impoundments. As noted above, this will reduce radon emissions by approximately 95% compared to dry conditions. We recognize that operators may still have to add water at times to ensure that the uranium byproduct material or tailings remain saturated, particularly during standby or high-evaporation periods. However, we anticipate that the need for additional water will be much less than would be necessary to maintain one meter of liquid. Because these impoundments are separately required to comply with the

requirements at 40 CFR 192.32(a)(1), we concluded that such a management practice is generally available and contributes to the control of radon emissions as described more fully in Section IV.A.2.

The final rule requires that visual evidence of saturation must be recorded and maintained by the owner/operator of the non-conventional impoundment, which we anticipate can be obtained using a smartphone or a digital camera during the routine daily inspections required by NRC regulations. Written observations must be recorded daily, with digital photographs to be taken at least weekly. Photographs including embedded metadata must be uploaded to the Subpart W Impoundment Photographic Reporting (SWIPR) Web site maintained by the EPA on at least a monthly basis, beginning on the effective date of this final rule.<sup>19</sup> Until that time, and subsequently should the SWIPR site be unavailable, digital photographs must be maintained by the facility owner/operator and provided to the EPA or authorized State upon request. Should the operator determine that the liquid has fallen to a level that exposes solid materials, the operator must correct the situation within one week, or other such time as specified by the EPA or the authorized State. This provides flexibility if the operator needs to take the impoundment out of service for a longer period to address the situation, such as to repair the liner. Photographs must be taken that show conditions before and after the liquid level is adjusted to verify that appropriate corrective actions have been taken. There is no limit on the size or number of non-conventional impoundments.

## 2. What key comments did we receive on non-conventional impoundments?

We received a variety of comments related to non-conventional impoundments. Many were related to the proposed requirement to maintain one meter of liquid in the impoundment. Others related to the potential for radon emissions from liquids in the impoundments, and whether those risks were properly characterized.

*Comment:* Many commenters opposed the proposed requirement to maintain one meter of liquid in the impoundment. Commenters primarily cited cost and the logistical difficulty of obtaining and transporting water as

making this proposed requirement overly burdensome, particularly in the arid West. A few commenters noted that impoundments that had already been approved and operating were not constructed with a depth that could accommodate an additional meter of water, potentially necessitating costly renovation. Other commenters noted that this requirement would have effects on the facility operation, where it is necessary to manage evaporative or holding capacity, and to control the characteristics of liquids that may be recycled through the process. The additional stress on the impoundment liner was also raised.

Some commenters questioned the need for this requirement, and noted statements in previous rulemakings that the difference between saturation and one meter of water is negligible. Commenters further argued that non-conventional impoundments present a small risk in any case. A few commenters suggested that a better approach would be to require that solid materials in the impoundment remain saturated, with no solids visible above the liquid level.

*Response:* We recognize the concerns raised regarding maintaining one meter of liquid in non-conventional impoundments. Because we determined that radon emissions can be controlled if the solids in non-conventional impoundment remain saturated, the final rule does not include a requirement to maintain one meter of liquid in the impoundments. Instead, the final rule adopts the approach suggested by the commenters. Solid materials in the impoundment must remain saturated, with no solids visible above the liquid level. This will achieve a reduction of roughly 95% compared to emissions from dry material. Saturation must be documented by written and visual records, with digital photographs taken on at least a weekly basis. We disagree that the non-conventional impoundments present such a small risk that they need not be regulated under Subpart W.

*Comment:* Commenters find difficulties in measuring compliance with the proposed one meter liquid requirement. One commenter believes direct measurements will be difficult because of the density of sediments and may present health and safety risks to workers. The commenter suggests that calculations based on mass and liquid balances would be more effective. Another commenter makes a similar suggestion, that the one meter requirement be replaced with a calculation to take into account site-specific factors and give operators

<sup>19</sup> SWIPR is accessed through the EPA's Central Data Exchange (CDX) (<https://cdx.epa.gov>). Information submitted to SWIPR is available to the public after review.

greater flexibility. A third commenter sees problems with the slope of the impoundment and the distance that must be observed, and notes that past experience suggests that measuring devices (such as pressure transducers) will need frequent maintenance and calibration. The commenter prefers to have a simple permanent indicator allowing visual confirmation, rather than measurement.

*Response:* We appreciate these comments and thoughtful suggestions. The final rule does not include a requirement to maintain one meter of liquid in the impoundments. Instead, the final rule requires that solid materials in the impoundment must remain saturated, with no solids visible above the liquid level. Although we proposed a one meter liquid cover, comments and further evaluation persuaded us that keeping solids saturated controls emissions nearly as effectively as maintaining a one-meter liquid cover. As explained in Section IV.E.1, we have recognized that keeping uranium byproduct material or tailings wet helps to limit radon emissions. We have further recognized that the difference between uranium byproduct material or tailings that are saturated and those covered with one meter of liquid is negligible. See Section IV.E.1 and 79 FR 25398.

*Comment:* Some commenters argue that the potential for radon emissions from non-conventional (liquid) impoundments has been greatly understated. They state that the general position taken by regulatory agencies (including the EPA) and industry that these impoundments represent a negligible source of radon compared to the solids in conventional impoundments is not supported by data. In particular, the commenters believe that radium in solution or suspension in the liquids has been overlooked as a potential source of radon, compared to solids or sediments in the bottom of the non-conventional impoundments. Commenters cited data from the 2013

and 2014 “Annual Tailings System Wastewater Sampling Report” submitted by Energy Fuels to the State of Utah to support this contention. Using radium data from liquid samples collected from Cells 1, 3, 4 and 4A at the White Mesa Mill and a correlation to radon flux from liquids in the EPA’s risk assessment to support the rulemaking (the “Task 5” report, Docket No. EPA–HQ–OAR–2008–0218–0123), the commenters calculate radon fluxes well in excess of 20 pCi/m<sup>2</sup>-sec (up to 2,317 pCi/m<sup>2</sup>-sec from Cell 1 in 2014). The commenters further note a significant increase in the radium measurements for three of the four impoundments from 2013 to 2014, likely attributable to evaporation and concentration of the radium in solution (Cell 3 showed a significant increase from 2012 to 2013, but dropped in 2014). They conclude that the risk to public health associated with radon emissions from non-conventional impoundments is much greater than the EPA has acknowledged.

*Response:* The EPA disagrees that the data provided by commenters support their conclusion that the liquids have been underestimated as a source of radon. First, the laboratory analyses included in the sampling report refer to “Total Alpha Radium” (or “Gross Radium Alpha”) and specify the analytical method as EPA Method 900.1.<sup>20</sup> This method cannot distinguish between different alpha-emitting isotopes of radium, which are all chemically identical. In addition to Ra-226, the isotope of concern that decays to form Rn-222, the sample may also contain Ra-224 (a decay product of Thorium-232) and Ra-223 (a decay product of Uranium-235). Because of the vast difference in their decay rates,<sup>21</sup> Ra-224 and Ra-223 need be present in much smaller amounts (by mass) to have the same activity as Ra-226. For example, one gram of Ra-226 will have the same activity as about 6.25 micrograms (6.25 x 10<sup>-6</sup> grams) of Ra-224. It is known that the White Mesa Mill has processed materials containing

Th-232, which makes it likely that Ra-224 is present in some amount. Given these sources of uncertainty, these results cannot definitively represent Ra-226 concentrations. Other sources of uncertainty could include interference from barium present in the liquid sample, as Method 900.1 relies upon precipitation with barium sulfate to separate the radium. Moreover, while Method 900.1 can essentially separate uranium from the sample, it is less effective at separating other alpha-emitting radionuclides, such as isotopes of thorium. Thus, some small amounts of uranium and thorium could solubilize and “carryover” into the precipitated sample, which would also affect the analysis. Given the numerous uncertainties associated with the data relied upon by the commenters, these data cannot reliably serve as a surrogate for Ra-226. Without specific isotopic analyses, which were not performed on the samples presented in the 2013 and 2014 reports, the actual Ra-226 concentrations cannot be determined.

The 2015 annual wastewater sampling report for White Mesa<sup>22</sup> contains additional information to clarify this situation. Samples taken on two separate occasions from each of the cells (compared to the single sampling conducted in previous years) were analyzed not only for total alpha radium, but also for the isotope Ra-226, using EPA Method 903.1 (“Prescribed Procedures for Measurement of Radioactivity in Drinking Water,” Docket No. EPA–HQ–OAR–2008–0218). These results confirm that total alpha radium is not the correct basis for calculations of radon emissions. Table 4 below shows the 2015 results for Cell 1, compared to the 2013 and 2014 results that were cited by the commenters. Cell 1 has been in use since 1981, and has only been used to manage liquids (*i.e.*, no solids from the mill have been placed in it). It consistently shows among the highest levels of total alpha radium.

TABLE 4—MONITORING RESULTS FROM CELL 1 AT THE WHITE MESA MILL

	Total alpha radium (pCi/L)	Ra-226 (pCi/L)
2013 .....	32,700	Not analyzed.

<sup>20</sup> “Prescribed Procedures for Measurement of Radioactivity in Drinking Water,” EPA–600/4–80–032, August 1980, Docket No. EPA–HQ–OAR–2008–0218.

<sup>21</sup> Radium-226 has a half-life of 1,600 years, while Radium-224 and -223 have half-lives of 3.66 days and 11.43 days, respectively. EPA Method 900.1 has been used by drinking water systems to show compliance with the regulatory standard of 5 pCi/

L for combined Ra-226 and Ra-228, which is well below the activity found in effluents from uranium processing. Ra-228 is a pre-cursor of Ra-224 that decays by beta emission and has a half-life of 5.75 years. If the result is below 5 pCi/L using Method 900.1, there is no need for additional analysis. Half-life is the amount of time for one-half of the radionuclide to decay. Further, although Ra-223 and Ra-224 decay to form Rn-219 and Rn-220 (also

known as “thoron”), respectively, these isotopes of radon are also very short-lived (half-lives less than one minute each) and therefore are not considered to be of concern for exposures to the public.

<sup>22</sup> Environmental reports for the White Mesa Mill are available from the Utah Department of Environmental Quality at <http://www.deq.utah.gov/businesses/E/energyfuels/whitemesamill.htm>.

TABLE 4—MONITORING RESULTS FROM CELL 1 AT THE WHITE MESA MILL—Continued

	Total alpha radium (pCi/L)	Ra-226 (pCi/L)
2014 .....	331,000	Not analyzed.
2015 Sample 1 .....	73,800	829.
2015 Sample 2 .....	735,000	1,110.

Source: "2015 Annual Tailings System Wastewater Sampling Report," Energy Fuels.

The Ra-226 concentrations found in 2015 are consistent with historical data, also included in the sampling reports. For the period 1980–2003, the maximum concentration of Ra-226 recorded is 1,690 pCi/L, based on sampling from Cell 1, Cell 2, and Cell 3 (it is not specified which cell recorded the maximum concentration). Table 6 of the Task 5 report estimates that, based upon site-specific conditions at the White Mesa Mill, a Ra-226 concentration of 1,000 pCi/L in impoundment liquids would result in a radon flux of approximately 7 pCi/m<sup>2</sup>-sec. Using this correlation, the average radon flux from Cell 1 in 2015 would be slightly less than 7 pCi/m<sup>2</sup>-sec. The highest level of Ra-226 in 2015 from the other impoundments was 772 pCi/L in Cell 4A, which translates to a radon flux of about 5.4 pCi/m<sup>2</sup>-sec. Further, based on the maximum Ra-226 concentration recorded from 1980–2003, the calculated radon flux would be roughly 11.8 pCi/m<sup>2</sup>-sec. These results indicate that the radon flux from Ra-226 suspended or dissolved in liquids in the non-conventional impoundments at White Mesa is controlled to a level that is within the range that the EPA determined to be acceptable during the development of Subpart W, without taking additional measures.

These results are also consistent with information reported for liquid impoundments at ISL facilities (see Tables 7, 8 and 9 of the Task 5 report). They also suggest that the noteworthy fluctuations in recent years may not be directly attributable to the radium content of the liquids, but may result from the analytical method used. "Total" or "gross" analytical methods are generally considered screening tools whose results are more susceptible to other influences. Energy Fuels states that the individual isotopic analyses "show that the increasing gross alpha results are being caused by matrix interference due to the nature of the tailings solution and are not representative of gross alpha from radium concentrations in the solution" (Energy Fuels, 2015 annual wastewater sampling report, page 15). Similar fluctuations occurred for all the

impoundments (although, as noted earlier, Cell 3 showed a significant increase in 2013, with a decrease in 2014).

As an additional source of information, the facility's 2015 "Semi-Annual Effluent Monitoring Report" (July through December) provides radon monitoring data from air monitoring stations posted around the impoundments. The facility resumed monitoring for radon in 2013 and the data presented in Attachment J of the report show that emissions have been within the limits calculated to correspond to a 25 mrem annual dose for continuous exposure at each monitoring station. These limits serve as As Low As Reasonably Achievable (ALARA) goals for the facility.

In most cases, results are well below that level. The highest annual result (four consecutive quarters) can be seen for Station BHV-4, which is located directly south of the impoundments but still within the White Mesa facility boundary. A person located at this point during 2015 would have incurred a dose of approximately 16 mrem<sup>23</sup> (average quarterly results of roughly 0.31 pCi/L, compared to a calculated limit of 0.5 pCi/L). The single highest quarterly reading is listed at Station BHV-6, which is to the southeast of the impoundments at the facility boundary. The reading for the fourth quarter of 2013 is approximately 88% of the calculated limit (0.73 compared to 0.83, translating to a quarterly dose of about 5.5 mrem at that location). However, readings for the previous two quarters were recorded as zero and readings for the next quarters were significantly lower as well. There is fluctuation in these results as well, which depends to some extent on wind direction, but overall the results indicate that radon from the impoundments is not a significant public health concern.

Both the sampling data from the non-conventional impoundment cells and the radon data from the air monitoring stations at the White Mesa Mill support the EPA's conclusion that emissions

from the liquids in non-conventional impoundments represent a limited source of radon and does not support commenters' argument to the contrary.

*Comment:* Some commenters request clarification that Subpart W should not apply to impoundments that only contain water that has been treated to meet effluent limits. The commenters see this as having no regulatory benefit, but a potential additional cost to operators who must meet the more stringent requirements in 40 CFR 192.32(a)(1). Commenters also suggest we define a threshold level of radium or uranium content below which liquids no longer must be managed as uranium byproduct material or tailings.

*Response:* The purpose of Subpart W is to control radon emissions from sources containing uranium byproduct material or tailings at uranium recovery facilities. The EPA agrees that if an impoundment does not contain uranium byproduct material or tailings, it is not subject to the requirements of Subpart W. The EPA is not defining a concentration or level of radium or uranium at which treated liquids would no longer be considered uranium byproduct material or tailings. Instead, such impoundments can be identified and their status can be addressed during the construction application review under 40 CFR part 61, subpart A.

Subpart W also does not apply to impoundments constructed for the purpose of managing liquids generated by closure or remediation activities, when they are used solely for that purpose. Impoundments that do not contain uranium byproduct material or tailings resulting directly from uranium recovery operations are not considered to be non-conventional impoundments as defined in Subpart W.

However, non-conventional impoundments remain subject to the requirements of Subpart W until they enter final closure pursuant to an approved reclamation plan for that impoundment, even if at some point in their operational life they are used for the purpose of managing liquids from closure or remediation activities. EPA recognizes that non-conventional impoundments that are subject to

<sup>23</sup> Corresponding to an annual risk of fatal cancer of less than  $1 \times 10^{-5}$ . See Section 4 of the BID.

Subpart W may subsequently transition to a use that supports facility closure or site remediation (e.g., when an ISL wellfield enters into the groundwater restoration phase, and is no longer recovering uranium). Some parties may argue that a non-conventional impoundment's receipt of waste associated with facility closure or site remediation appears analogous to the ability of licensees to obtain a license amendment and have a reclamation plan which provides for placement of remediation wastes in conventional impoundments during the closure process. Using this analogy, some may contend that non-conventional impoundments should not be subject to Subpart W when receiving such wastes. However, such a non-conventional impoundment could later be used to manage liquids from uranium recovery operations at the next wellfield. To ensure that non-conventional impoundments that receive uranium byproduct material and tailings are managed in accordance with Subpart W, and to promote clarity and consistency with the promulgated regulations, Subpart W applies to non-conventional impoundments during the entire operating life of an impoundment which receives, or has received, uranium byproduct material or tailings directly from active uranium recovery operations. Changing a non-conventional impoundment's Subpart W applicability based on the primary use of the impoundment at any particular time during its operational life would cause unnecessary confusion and would be inconsistent with the regulations.

Operationally, this should not represent a burden to licensees. If the impoundment is being used to manage liquids from closure or remediation activities, it should remain in compliance with the requirement to retain sufficient liquid to cover solid materials in the impoundment. Further, because there is no restriction on the number of such impoundments that may be operating at one time, the licensee will not face the same pressure to begin closure as applies to conventional impoundments using the phased disposal approach.

*Comment:* A commenter finds the discussion of non-conventional impoundments confusing. The commenter believes we have inconsistently and inaccurately described the purpose of these impoundments, the nature of the materials in them, and our regulatory approach. The commenter wishes us to clarify that the liquids are not held in the impoundments for the purpose of

covering uranium byproduct material or tailings, but the liquid in fact contains (or is) uranium byproduct material or tailings. The commenter questions how the liquid can be used to control radon emissions, when the liquid is itself in need of control, and requests that we consider that liquids high in radium content may actually cause an increase in emissions.

*Response:* The purpose of non-conventional impoundments (evaporation or holding ponds) is to receive liquids generated by the uranium processing operation. Uranium byproduct material or tailings may be suspended or dissolved in these liquids. Some portion of the material will precipitate out and settle on the bottom of the impoundment. In some sense, the liquid itself is uranium byproduct material or tailings because it is a waste from the concentration or extraction process. The definition of "non-conventional" impoundment accurately conveys the concept that these impoundments "contain uranium byproduct material or tailings suspended in and/or covered by liquids." As noted in the previous comment response, impoundments containing only treated water and impoundments constructed for the purpose of managing liquids from closure or remediation activities are not non-conventional impoundments as defined by Subpart W, because they do not contain uranium byproduct material or tailings resulting directly from active uranium recovery operations.

While radium contained in the liquid will contribute to radon emissions, those emissions will be attenuated to some degree by the liquid in which it is contained. Further, liquid on top of solid materials will effectively limit radon emissions from those solids reaching the air, even if the liquid itself contains radium. While higher concentrations of radium in the liquid will generate more radon, concentrations in non-conventional impoundments have not been seen to reach levels of concern. See the response to the earlier comment in this section.

*Comment:* Many commenters expressed opinions related to limiting the size of impoundments. Some commenters believe Subpart W should contain limits on the size of non-conventional impoundments. The commenters believe that larger impoundments are more likely to fail and limits must be imposed to minimize the potential for ground water contamination. One commenter also believes the number of impoundments should be limited. Another commenter

does not believe we have adequately supported our conclusion that the requirements of 40 CFR 192.32(a)(1) will provide protection against extreme weather events and may be subject to greater turbulence. Regarding our reference to an impoundment of 80 acres, one commenter wishes us to clarify that no actual impoundment has been as large as 80 acres, but this size has been used only for modeling purposes. Another disputes our statement that it is reasonable to assume that such impoundments will not exceed 80 acres in area, simply because one never has.

*Response:* We have chosen not to limit the size of non-conventional impoundments because they are not as significant a source of radon emissions and can be readily controlled by maintaining saturation of solid materials, but also because they provide operational flexibility to uranium recovery facilities that may need to manage, on a temporary basis, large volumes of water that can then be recycled into the process. Regarding the maximum size of such impoundments, we referred to 80 acres as a "reasonable maximum approximation" for estimating cost, clearly noting that it is "the largest size we have seen" (79 FR 25401).

*Comment:* A commenter states that the current and proposed rules do not actually contain any measures to control releases of impoundment contents to the surface or subsurface during extreme weather events. The commenter asserts that the EPA has not provided any data to support the conclusion that the requirements of 40 CFR 264.221 will prevent dispersion of contents in severe events. The commenter expresses concern that generally available technologies do not exist that could prevent dispersion of contents or failure of the impoundment in a severe event such as a tornado or hurricane.

*Response:* As discussed in the proposal, we believe the design and engineering requirements for impoundments in 40 CFR 264.221, referenced in 40 CFR 192.32(a)(1), provide a sound basis for protection against reasonably foreseeable weather events. The provisions related to avoiding overtopping (essentially, spillage or dispersion) from "normal or abnormal operations," "wind and wave action," or "rainfall," as well as the requirement to maintain integrity and prevent massive failure of the dikes, lay a foundation for addressing the commenter's concerns. To satisfy these conditions, design of impoundments at any specific site would likely take into account regional climate and the

magnitude of events such as 100- or 500-year precipitation, or the likelihood of tornados or hurricanes.

*F. Definitions, References and Conforming Editorial Revisions*

1. How did we address definitions, reference and conforming editorial revisions in the proposed and final rules?

a. Definition of “Operation” and “Final Closure”

We proposed a relatively minor change to the definition of “operation” (79 FR 25404). Under Subpart W as promulgated in 1989, an impoundment was in operation when new tailings were being emplaced, from the day that tailings are first placed in the impoundment until the day that final closure begins. There has been some confusion over this definition. We proposed to amend the definition of “operation” in the Subpart W definitions at 40 CFR 61.251 to replace the reference to “new” tailings with the broader term “uranium byproduct material or tailings” at 79 FR 25405.

We received comments from across the spectrum of stakeholders who disliked this definition. Commenters from industry said we did not take into account the period between cessation of placement of uranium byproduct material or tailings into an impoundment and physical closure with an approved closure plan. This period can sometimes last for years while the uranium byproduct material or tailings are dewatered to an extent that heavy machinery can be used to emplace the final closure radon barrier. Also, the impoundment(s) are often used for dismantling the facility, for disposal of other liners, etc. Extending the operational period and Subpart W jurisdiction during the entire closure period could result in a milling facility having two operating impoundments in the closure process and no ability to operate a third impoundment to receive uranium byproduct material or tailings from operations. Other commenters claimed that operators were taking advantage of the existing definition by claiming that an impoundment is “in closure” but taking no concrete action to implement a closure plan or apply a final cover.

We do not intend to extend the jurisdiction of Subpart W to include the period during which closure activities are being conducted. The proposal was intended to clarify that an impoundment remains “operating” until it enters closure, even if it is not receiving newly-generated uranium byproduct material or tailings from

facility processing (79 FR 25405). Further, we note that the definition in Subpart W is consistent with those in 40 CFR 192.31 and 10 CFR part 40, Appendix A, which were in fact derived from Subpart W. Thus, we find this concern to be misplaced. The final rule adopts the definition of “operation” as it was proposed.

We did not propose to include a definition of “closure”; however, we realize that a lack of clarity on the concept of closure, what it involves and when it begins has affected the understanding of Subpart W. In particular, the use of the term “final closure” in the definition of “operation” does not, by itself, provide sufficient clarity on the end of operation. As described earlier, we received a number of comments making suggestions or raising concerns on this point. As noted above, the definition of “operation” in Subpart W served as the basis for the definitions later adopted in 40 CFR part 192 and 10 CFR part 40, Appendix A. Further, both 40 CFR part 192 and 10 CFR part 40, Appendix A adopted definitions and requirements related to closure that address some aspects of the comments we received related to Subpart W. The more appropriate action is to retain the definition of “operation” and clarify the meaning of final closure in a separate definition. Therefore, the final rule incorporates a new definition of “final closure” at 40 CFR 61.251(n).

We emphasize two aspects of this new definition that we believe will help address concerns regarding the timeliness and predictability of closure activities. First, impoundments or heap leach piles will remain subject to Subpart W until the owner or operator provides written notice that the impoundment is entering final closure. Second is the reference to the reclamation plan for the impoundment or heap leach pile. We have heard some comments, specifically related to the Cotter mill, that the facility should still be subject to Subpart W because it has never had an approved reclamation or closure plan; however, the facility no longer has an operating license under which it would conduct activities subject to the requirements of Subpart W.

The reference to a reclamation plan in the definition of “final closure” does not affect that Subpart W only applies to operational units and does not cover units that are in closure. Rather, it makes clear our expectation, also found in 40 CFR part 192 and 10 CFR part 40, Appendix A, that the NRC or the Agreement State require and approve such a plan. It also establishes that notice to the NRC or the Agreement

State and an approved reclamation plan are necessary prerequisites for determining that the impoundment in question is no longer subject to the requirements of Subpart W. The final rule is adopting the terminology employed in NRC regulations. In 10 CFR part 40, Appendix A, NRC identifies a reclamation plan as applicable to individual impoundments, while the closure plan is a more comprehensive document that addresses all aspects of facility closure and decommissioning, including any necessary site remediation. A reclamation plan prepared and approved in accordance with NRC requirements in 10 CFR part 40, Appendix A, is considered a reclamation plan for purposes of Subpart W. The reclamation plan may be incorporated into the larger facility closure plan.

A number of commenters expressed concern that the issue of delayed closure would have been addressed by 40 CFR part 61, subpart T (40 CFR 61.220–226), which required that impoundments that are no longer accepting tailings be brought into compliance (*i.e.*, covered) within two years, or in accordance with an approved compliance agreement if it is not feasible to complete closure within two years. In accordance with a 1991 Memorandum of Understanding (MOU), the EPA and the NRC amended 40 CFR part 192 and 10 CFR part 40, Appendix A, respectively, to incorporate provisions related to the timing and requirements of activities conducted during the closure period. The EPA subsequently rescinded subpart T in 1994, finding that the NRC regulatory program protected public health with an ample margin of safety to the same level as would implementation of subpart T (59 FR 36280, July 15, 1994). The commenters correctly noted that in that action the EPA retained the authority to reinstate subpart T should we determine that the NRC was not implementing it as we intended. The Agency has no plans to reinstate subpart T at this time, but takes this opportunity to emphasize that closure of impoundments should be conducted expeditiously, taking only the time that is truly necessary to dewater or otherwise prepare the uranium byproduct material or tailings before application of interim and final covers.

b. Liner Requirements in 40 CFR 192.32(a)(1)

We proposed specific provisions for conventional impoundments, non-conventional impoundments and heap leach piles to explicitly convey that any impoundment at a uranium recovery

facility that contains uranium byproduct materials or tailings would be subject to the Subpart W liner requirements. The 1986 and 1989 versions of Subpart W included a reference to 40 CFR 192.32(a); 40 CFR 192.32(a) incorporates the surface impoundment design and construction requirements of hazardous waste surface impoundments regulated under the Resource Conservation and Recovery Act (RCRA), found at 40 CFR 264.221. Those requirements state that the impoundment shall be designed, constructed and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil or ground water or surface water at any time during the active life of the impoundment. Briefly, 40 CFR 264.221(c) requires that, for new impoundments constructed after January 29, 1992,<sup>24</sup> the liner system must include:

1. A top liner designed and constructed of materials (e.g., a geomembrane) to prevent the migration of hazardous constituents into the liner during the active life of the unit.

2. A composite bottom liner consisting of at least two components. The upper component must be designed and constructed of materials (e.g., a geomembrane) to prevent the migration of hazardous constituents into this component during the active life of the unit. The lower component must be designed and constructed of materials to minimize the migration of hazardous constituents if a breach in the upper component were to occur. The lower component must be constructed of at least three feet of compacted soil material with a hydraulic conductivity of no more than  $1 \times 10^{-7}$  cm/sec.

3. A leachate collection and removal system between the liners, which acts as a leak detection system. This system must be capable of detecting, collecting and removing hazardous constituents at the earliest practicable time through all areas of the top liner likely to be exposed to the waste or liquids in the impoundment.

There are other requirements for the design and operation of the impoundment, and these include construction specifications, slope requirements, sump requirements and liquid removal requirements. As part of the proposed rule, we examined these provisions to help determine whether Subpart W adequately addresses extreme weather events. We determined

<sup>24</sup> 57 FR 3487, January 29, 1992. These specifications also apply to lateral expansions of existing surface impoundment units or replacements of existing surface impoundment units beginning construction or reuse after July 29, 1992. At the time of the 1986 and 1989 Subpart W rulemakings, double liners and leachate collection systems were specified for new impoundments, but the requirements did not contain this level of detail. The requirement for double liners was promulgated on July 15, 1985 (50 FR 28747).

that the requirements in 40 CFR 264.221 satisfactorily address such events.

The proposal did not adopt a new approach. Instead, it carried forward the approach adopted in the 1989 rulemaking. That rulemaking included § 61.252(c), which broadly required all impoundments, including those in existence prior to the promulgation of 40 CFR part 192, to comply with the requirements of 40 CFR 192.32(a). The 1986 rulemaking had not applied the requirements of 40 CFR 192.32(a) to impoundments in existence when the 1986 rule was promulgated, as these impoundments were anticipated to cease accepting uranium byproduct material or tailings by the end of 1992 (51 FR 34066). The 1989 rulemaking lifted this restriction as well as the exemption from the requirements of 40 CFR 192.32(a) (54 FR 51680).

We did not propose to remove the liner requirements or request comment on whether they should be retained. We proposed to refer only to 40 CFR 192.32(a)(1) because § 192.32(a) includes provisions that extend well beyond the design and construction of impoundments, such as ground water monitoring systems and closure requirements. These aspects do not fall under the purview of Subpart W, and they are removed in this action.

This final rule incorporates the revised reference to 40 CFR 192.32(a)(1) for all impoundments that contain uranium byproduct material or tailings and establishes this requirement as an element of GACT-based standards for conventional impoundments, non-conventional impoundments, and heap leach piles. The provision in the 1989 rule that extended this requirement to conventional impoundments in existence as of December 15, 1989 is moved to § 61.252(a)(1), which addresses those impoundments.

We received a comment suggesting that we explicitly cite 40 CFR 264.221(c) as the criteria that all impoundments are required to meet. This provision was not incorporated into regulation until 1985 (50 FR 28747). Adopting the commenter's approach would require impoundments constructed before 1985 to upgrade or close, which we did not propose to require. Those older impoundments are required to comply with the provisions of 40 CFR 264.221 that are applicable to them. The commenter's approach would also eliminate consideration of § 264.221(d), which allows for an alternative design or operating practices if "such design and operating practices, together with location characteristics" would prevent migration of hazardous constituents and allow detection of leaks at least as

effectively as the requirements of § 264.221(c). It is not appropriate to eliminate this flexibility, particularly for sites that may employ improved liner materials or have exceptional natural characteristics that lend themselves to such a demonstration.

c. Eliminating "As Determined by the Nuclear Regulatory Commission"

As described in the preceding section, Subpart W as promulgated in 1989 required impoundments to be constructed in accordance with the requirements cited in 40 CFR 192.32(a). This provision also included the phrase "as determined by the Nuclear Regulatory Commission."

As described in the preceding section, 40 CFR 192.32(a) also contains provisions related to ground water protection and closure activities, which are not within the scope of Subpart W. It is appropriate that the NRC be the sole regulatory agency for implementing and enforcing these provisions. We proposed to eliminate the phrase "as determined by the Nuclear Regulatory Commission" from Subpart W to clarify that EPA is an approval authority for Subpart W, but specifically for the impoundment engineering and construction requirements in 40 CFR 192.32(a)(1).

We received a number of comments from industry objecting to this change on the grounds that it would create dual regulation with NRC, thus leading to inefficiencies and the potential for one agency to approve an application while the other denied it. We disagree with these commenters, as described in detail in the next section. The final rule eliminates the phrase "as determined by the Nuclear Regulatory Commission" from 40 CFR 61.252(a)(2)(i) and (ii).

2. What key comments did we receive on definitions, references and conforming editorial revisions?

We received a number of comments related to the issue of operation and closure, either to extend the jurisdiction of Subpart W or to limit it. Commenters also expressed views on the liner requirements and their relation to groundwater protection or older impoundments. In connection with the liner requirements, a number of commenters disagreed with the proposal to eliminate the phrase "as determined by the Nuclear Regulatory Commission," suggesting that it will create dual regulation and exceeds our rulemaking authority. Although we did not propose to revise it, we also received some comment related to the definition of "uranium byproduct material or tailings."



*Comment:* A number of commenters advocated that the scope of Subpart W be extended to include all activities undertaken to achieve final closure of the impoundment (see also the next comment in this section). As defined in Subpart W, “operation” ends “the day that final closure begins” (40 CFR 61.251(e)). Many of the commenters would like this definition extended and explicitly stated that Subpart W should apply until the final cover is installed on the impoundment (or, for non-conventional impoundments, until the impoundment is removed, if that is the closure approach).

*Response:* Subpart W has never addressed remediation or reclamation activities undertaken to close the impoundment or the site and EPA did not propose to expand the scope of the rule to cover such activities. Comments on whether the separate regulations that apply during closure and until the final cover is installed are sufficient or whether additional regulations are needed to cover activities during that time period are beyond the scope of this section 112(q) review of Subpart W and thus EPA has no obligation to respond. However, a goal of this rulemaking was to provide clarity regarding when the management of uranium byproduct material or tailings is no longer subject to Subpart W. The final rule specifies that Subpart W no longer applies at the beginning of closure and further defines when closure begins. For informational purposes only, EPA discusses below some of the regulations that apply during the closure period. EPA did not reopen or accept comment on any aspects of these regulations.

In 1989, in conjunction with the promulgation of Subpart W, the EPA promulgated 40 CFR part 61, subpart T (40 CFR 261.220–226) to address the closure period and final disposal for conventional tailings impoundments (54 FR 51682). Subpart T required closure of impoundments to be complete within two years after ceasing operations.

In 1991, by Memorandum of Understanding (MOU) with the NRC, the two agencies agreed to take action to clarify the timing for closure of impoundments and processing sites. As part of this agreement, the EPA amended 40 CFR part 192 (58 FR 60341, November 15, 1993) and rescinded subpart T (59 FR 36302, July 15, 1994). The NRC subsequently amended 10 CFR part 40, Appendix A, consistent with the EPA’s amended 40 CFR part 192 (59 FR 28220, June 1, 1994). The MOU included the goal that all sites could be closed and in compliance with radon emission standards by 1997 or within seven years of the date on which

existing operations cease and standby sites enter disposal status. The MOU did not address Subpart W because Subpart W does not apply during closure.

The MOU and subsequent regulatory actions created a more comprehensive and coordinated framework for managing uranium processing wastes. Further, a settlement agreement with stakeholders provided additional detail to the MOU that, in part, allowed the EPA to make a finding under the CAA that the NRC’s regulatory program protected public health with an ample margin of safety. This supported the Agency’s decision to rescind subpart T.

In their respective rulemakings, the agencies essentially adopted the Subpart W definition of “operation” and included provisions related to closure that would allow certain activities related to waste management during the closure process. Among these were provisions that would allow wastes to be placed in impoundments that were also either in closure or had completed closure (final cover). These authorizations would not change the status of the impoundment or site, as we explained in our rulemaking to amend 40 CFR part 192: “Even if a portion of a site is authorized to remain accessible for disposal of byproduct materials during the closure process or after placement of a permanent radon barrier consistent with the Settlement Agreement, as described above, this will not cause a nonoperational uranium mill tailings disposal site to revert to an operational site as defined by 40 CFR 192.31(q)” (58 FR 60348, November 15, 1993).

Similarly, the NRC addressed this point in its 1993 proposed rule to amend 10 CFR part 40, Appendix A in response to a comment from an NRC Agreement State:

*[Agreement State] Comment.* The word “portion” should be deleted from paragraph (3) of Criterion 6A.

*[NRC] Response.* This provision allows limited disposal during closure as an exception to the definition of *operation*. If the whole impoundment is involved in waste disposal and no reclamation activities are proceeding, the impoundment would be considered operational and continue to be under appropriate requirements for operation. Note, one site may have both an operational impoundment and a non-operational impoundment with the applicable regulations applying to each (58 FR 58659, November 3, 1993, emphasis in original).

The final rule includes the definition of “operation” as it was proposed, which makes it fully consistent with the definitions in 40 CFR part 192 and 10 CFR part 40, Appendix A. We are also adopting a definition of “final closure”

that clarifies that Subpart W does not apply to impoundments that are being managed under an approved reclamation plan for that impoundment or the facility closure plan.

*Comment:* Several commenters stated that the current regulatory scheme allows an unacceptable period during closure activities when impoundments are not being monitored or otherwise managed to limit radon emissions. They further argue that closure is not being conducted in a manner that will lead to timely installation of a final cover or removal of an evaporation or holding pond. They cite periods of decades during which tailings are being “dewatered” or impoundments are used to deposit wastes from decommissioning activities, while the drying-out of impoundments allows increased radon emissions. Commenters attribute this in some part to the Agency’s rescission of subpart T, which called for installation of final covers on conventional tailings impoundments within two years of the cessation of operations. One commenter notes that an impoundment undergoing closure will be required to demonstrate compliance with the 20 pCi/m<sup>2</sup>-sec radon emissions standard only if it requests extension of the milestones in the closure plan, where it may not have been required to monitor previously under Subpart W.

*Response:* The EPA did not propose to extend the jurisdiction of Subpart W beyond the operational phase, nor did we request comment on regulations that are applicable to closure activities. We are under no obligation to respond to such comments. However, one purpose of this rulemaking was to clarify at what point Subpart W no longer applies to the management of uranium byproduct material or tailings. The final rule specifies that Subpart W no longer applies at the beginning of closure and further defines when closure begins. The following response is provided in the interest of further clarifying this issue.

As described in the response to the previous comment, the EPA and the NRC entered into an MOU in 1991, after industry efforts to stay the implementation of subpart T, due, in part, to the fact that the requirement to complete closure of impoundments was unrealistically stringent. As part of the MOU, the EPA rescinded subpart T and modified its UMTRCA standards at 40 CFR 192.32 to address activities conducted during closure, including allowing placement of decommissioning wastes in non-operating impoundments. The EPA and the NRC agreed that such activities can, for the most part, be

conducted and a final cover installed within seven years of the end of operations. Similar timeframes should be possible for non-conventional impoundments, which are likely to be removed altogether. We note that both 40 CFR 192.32(a)(3) and 40 CFR part 40, Appendix A were modified and require that closure take place “as expeditiously as practicable considering technological feasibility.” They further state that such placement of wastes during closure will not be approved if it would cause delays in emplacement of the final radon barrier to meet the disposal requirements. The MOU did not address Subpart W because Subpart W does not apply during closure.

The Agency has no plans to reinstate subpart T, although EPA is not precluded from doing so (40 CFR 261.226). Nor is the final rule extending the scope of Subpart W to cover closure activities. While this does leave a period of time when conventional and non-conventional impoundments are more likely to have increased radon emissions because they are not managed as they would be during operations, such a period is necessary to facilitate final closure activities. However, “dewatering” tailings for decades, particularly in the arid West, is certainly not consistent with the seven-year period envisioned by both the EPA and the NRC. Most conventional tailings are emplaced using the phased disposal method. To avoid extended dewatering periods, sites may consider using the continuous disposal method, in which tailings are dewatered before emplacement and immediately covered. Regardless of the method of emplacement, we emphasize the importance of timely closure in achieving the safe end state of these sites, and encourage the NRC and NRC Agreement States to give appropriate attention to controlling radon emissions during closure activities.

*Comment:* Some commenters expressed concern that impoundments are not being closed in accordance with closure plans, because the plans do not exist, milestones are absent or unclear, or milestones are not being enforced. One commenter states that the EPA should not consider an impoundment in closure until such plans are incorporated into the facility license. Another commenter recommends that we amend 40 CFR part 192 to include a provision that the EPA will verify the existence of a closure plan. Several commenters offer specific comments related to the White Mesa and Cotter sites and what they perceive as a lack of closure plans.

*Response:* Activities related to closure or closure plans are beyond the scope of this rulemaking and the EPA is under no obligation to respond to comments on that topic. However, one purpose of this rulemaking was to clarify at what point Subpart W no longer applies to the management of uranium byproduct material or tailings. This final rule specifies that an approved reclamation plan is a prerequisite for entering closure, thereby removing a unit managing uranium byproduct material or tailings from the jurisdiction of Subpart W. The response below is provided in the interest of clarity in conveying the provisions of the final rule. The EPA does not require, review, approve or enforce reclamation or closure plans.

As noted by one commenter, closure plans with milestones are required under 40 CFR part 192 and 10 CFR part 40, Appendix A. Closure plan requirements, closure activities and revisions to part 192 are not within the scope of this Subpart W rulemaking. The EPA typically does not see closure plans when reviewing construction applications under 40 CFR part 61, subpart A. The NRC or the Agreement State is responsible for enforcement of reclamation or closure plans. The Cotter site ceased operations several years ago, no longer has an operating license and is therefore no longer subject to the requirements of Subpart W. The site is currently a Superfund site and is conducting activities under a decommissioning license from the State of Colorado.

The final rule includes a definition of “final closure” that specifies notification that the impoundment in question is being managed according to the requirements and milestones in the approved reclamation plan. This should provide clarity when determining whether an impoundment is in closure, and whether Subpart W still applies.

*Comment:* A few commenters took the opposite view of that addressed earlier in this section. These commenters wish us to clarify that the period of operations for either a conventional or non-conventional impoundment only extends to the management of uranium byproduct material or tailings produced by the concentration or extraction of ore processed primarily for its source material content (which may include the commercial management of such wastes produced at other facilities), and not to the management of wastes (byproduct material or otherwise) generated during closure or decommissioning activities.

*Response:* The final rule clarifies that Subpart W does not apply during

closure activities, and further defines when final closure begins. As described above in this section, this is essentially the position agreed to in the 1991 MOU between the EPA and the NRC. Both 40 CFR 192.32(a)(3) and 10 CFR part 40 Appendix A, Criterion 6(A) provide for the use of impoundments while they are undergoing closure. However, impoundments that are used to manage uranium byproduct material or tailings generated during closure or remediation activities, while remaining open to manage operational wastes, would continue to fall under Subpart W until they formally enter the closure process and implement the approved reclamation plan for that impoundment. The definition of “final closure” adopted in the final rule makes clear that Subpart W does not apply to impoundments that are being managed under an approved reclamation plan.

In addition to the use of an impoundment for wastes generated during closure or remediation activities, NRC regulations also provide for waste from other sources to be emplaced in the impoundment during the closure process (10 CFR part 40, Appendix A, Criterion 6(A)(3)). Approval of such emplacement requires a license amendment and must not delay complete closure of the impoundment. Subpart W does not apply to such authorized emplacements while the impoundment is undergoing closure because the unit is subject to an approved reclamation plan and, therefore, no longer operating. Depending on the terms of the license amendment, authorized emplacements at impoundments may include waste from ISL sites, which are not expected to construct permanent impoundments, thereby facilitating the overall goal of limiting the number of small disposal sites. Authorization to allow emplacement of waste from other sources during the closure process must be reflected in both the facility license and the applicable reclamation plan.

*Comment:* One commenter disagreed with comments described earlier and pointed out that maintaining impoundments under Subpart W jurisdiction while they are undergoing closure may cause facilities to be out of compliance with the restriction on the number of conventional impoundments. The commenter posits that this situation could arise if a facility opened a new conventional impoundment for operational uranium byproduct material or tailings, while having another one in operation and one in closure (or multiple impoundments in closure). To avoid compliance issues, the commenter explained that facilities may have to

defer opening new impoundments, which could lead to temporary shutdown of the facility's processing operations if there is no outlet for the wastes. The commenter specifically notes that non-conventional impoundments may continue in operation when conventional impoundments are in closure.

*Response:* We did not propose to extend the scope of Subpart W to apply during closure activities and thus did not open this issue as part of our review under CAA section 112(q). Also, we are neither finalizing such an extension of applicability, nor limiting the number of non-conventional impoundments that may be in operation at any one time.

*Comment:* Several commenters stated that definitions in or proposed for Subpart W are inconsistent with the NRC's definitions in 10 CFR part 40 (and Appendix A). For example, two commenters state that "[t]he definition of *Operation* conflicts with existing regulations, specifically those in 10 CFR part 40 Appendix A following the rescission of 40 CFR part 61 Subpart T." These commenters also suggest that we look to the Appendix A definition of "closure" and they note that the closure period is tied to the "end of milling operations" in Criterion 6.

One commenter requests clarification of the term "day that final closure begins," which the commenter believes has never been adequately explained. Another commenter requests clarification on the steps that must take place for closure to begin. Commenters also stated that we did not include non-conventional impoundments in the definition of operation.

*Response:* It is important to make the distinction between closure of an impoundment and closure of a facility. Subpart W applies to impoundments that are operating. An individual impoundment may enter and complete the closure process, thus removing it from Subpart W jurisdiction, while other impoundments and the facility continue to operate. When the facility (site) itself enters the closure process, and is no longer operating (and generating uranium byproduct material or tailings), impoundments will also be managed according to the overall site closure plan. Tying Subpart W to the "end of milling operations" in NRC regulations, as suggested by the two commenters, would essentially preclude the closure of individual impoundments until overall site closure begins. This is likely contrary to the commenters' intentions. We also note that the NRC definition of "closure" cited by these commenters clearly refers to activities undertaken to close the entire site and

is not directed specifically at impoundment closure.

Additionally, commenters have misinterpreted our proposal. The Agency does not intend to apply Subpart W to impoundments that have entered the closure process. The proposed modification of the definition of "operation," which we are adopting in the final rule, clarifies that impoundments that have not yet entered closure remain subject to Subpart W, even if the material they are receiving is not newly-generated uranium byproduct material or tailings ("new tailings" in the original). This also makes the definition more consistent with those in 40 CFR part 192 and 10 CFR part 40, Appendix A. See the proposed rule at 79 FR 25405, May 2, 2014. To further clarify this situation, the final rule includes a definition of "final closure" specifying that closure begins upon written notification that the impoundment is being managed according to the requirements and milestones in the approved reclamation plan for that impoundment.

This definition of "final closure" adopts a suggestion provided by one commenter. The commenter proposed tying "closure period" to a written notification from the licensee that the impoundment is no longer being used for emplacement of tailings or for evaporative or holding purposes, and is also no longer on standby for such purposes. The commenter suggests that it would be useful to explicitly address both conventional and non-conventional impoundments in the definitions, as there may be situations where non-conventional impoundments continue to operate when conventional impoundments are in closure. We are also adopting this suggestion in the definition of "final closure."

Adding this language should eliminate some uncertainty regarding impoundment status. This uncertainty is reflected in a statement by the same commenter regarding the White Mesa Mill. In providing information about the different impoundments, the commenter notes that ". . . Cell 3 *could be considered* to have already commenced the closure process" (emphasis added). The written notification requirement will help eliminate such ambiguous situations. There should be no question as to whether an impoundment is undergoing closure, and similarly no ambiguity regarding the applicability of Subpart W.

Regarding the perceived conflicts with NRC regulations, we do not see such a conflict, and note that the definition of "operation" in existing and proposed Subpart W is substantively

identical to and served as the basis for that in 10 CFR part 40, Appendix A (we note the NRC's statement in its proposal that "the definition of operations is in conformance with the definition of 'operational' in the proposed EPA amendment to [40 CFR part 192] subpart D and in 40 CFR part 61, subpart W" (58 FR 58659, November 3, 1993)). The commenters did not suggest that the NRC's definition is in conflict with its own regulations. Further, the same definition is used in 40 CFR 192.31(p). As noted above, we are also adding a definition of "final closure" in the final rule. This will provide additional clarity as to what steps the operator must take to remove an impoundment from the jurisdiction of Subpart W while remaining consistent with the definitions in 10 CFR part 40 and 40 CFR part 192. The definition of final closure explicitly addresses conventional impoundments, non-conventional impoundments and heap leach piles.

The phrase "day that final closure begins" was included in the original promulgation of Subpart W in 1986 (51 FR 34056, September 14, 1986). "Final closure" is a term defined under RCRA hazardous waste regulations in 40 CFR 260.10. "Final closure" in that context refers to the closure of all hazardous waste management units at a site, and is distinguished from "partial closure," which refers to closure of individual units. However, as the term is used in Subpart W, and as it is being adopted in the final rule, it refers to individual impoundments, not the entire site (so is more like "partial closure" in the RCRA context). Subpart W differs in this respect from 40 CFR part 192 and 10 CFR part 40, Appendix A, which are both also concerned with closure of the overall site. We also note that, as described earlier, the definition of "operations" in Subpart W served as the basis for corresponding definitions in 40 CFR part 192 and 10 CFR part 40, Appendix A, and this phrasing has also been adopted in and provides consistency with those regulations. We did not propose to change it and we are not finalizing any changes.

*Comment:* The State of Utah commented on the status of liners at two of the facilities regulated by the State under its Subpart W delegation. The conventional impoundment at the Shootaring Canyon Mill was constructed in 1981 and "was not required to be constructed in accordance with" the requirements of 40 CFR 192.32(a). However, the State will require the liner to be upgraded if the mill goes back into production. The Shootaring Canyon Mill operated for

only a short period and has been in standby for nearly 35 years. The State also addresses Cell 1 at the White Mesa Mill, which is a non-conventional impoundment also constructed in 1981. The State has not considered this impoundment to be subject to Subpart W and believes that EPA must conduct a cost-benefit analysis if the liner is required to be upgraded.

*Response:* Comments indicate that some stakeholders have not always clearly understood the true scope of the 1989 Subpart W rulemaking. The 1989 rulemaking revised the approach taken in 1986, which required impoundments existing at that time to cease operations by December 31, 1992 unless they could receive an exemption or extension (51 FR 34066). These impoundments were not required by Subpart W to meet the requirements of 40 CFR 192.32(a). The 1989 rulemaking lifted the operating restriction on older impoundments, but also removed the exemption from the requirements of 40 CFR 192.32(a) (54 FR 51680). This provision, promulgated as 40 CFR 61.252(c), explicitly addressed the exemption for impoundments constructed prior to the promulgation of 40 CFR part 192 and established that all impoundments used to manage uranium byproduct material or tailings became subject to the liner requirements in 40 CFR 192.32(a) when the 1989 rule became effective, regardless of when they were constructed. These liner requirements have remained in place because CAA section 112(q) explicitly retains standards that were in effect before the date of enactment of the CAA Amendments of 1990, unless and until the EPA revises them.

The two impoundments identified by the State of Utah are both required to comply with the liner requirements in 40 CFR 192.32(a)(1), and by extension 40 CFR 264.221. The standby status of the Shootaring Canyon Mill makes no difference in this regard. We understand that some stakeholders did not view the 1989 rulemaking as applicable to liquid (non-conventional) impoundments. This final rule clarifies that non-conventional impoundments did fall under the 1989 rule and are also subject to the requirements in 40 CFR 192.32(a)(1). We note that Denison Mines, the previous owner of the White Mesa Mill, stated in its response to the EPA's section 114 request for information that Cell 1 meets the requirements of 40 CFR 264.221(a).

*Comment:* Many commenters objected to the proposal to eliminate the phrase "as determined by the Nuclear Regulatory Commission" from provisions related to review of the impoundment construction requirements in 40 CFR 192.32(a)(1).

Commenters in general argued that eliminating the phrase "as determined by the Nuclear Regulatory Commission" would result in unnecessary dual regulation if both the EPA and the NRC need to review and approve construction applications, with limited if any benefit. One commenter suggests this will have significant cost implications that were not considered during the rulemaking. Another commenter questions how disagreements between the agencies will be resolved, and suggests that appeals will be "inappropriately complicated".

A number of these commenters asserted that our proposal was contrary to the legal framework established by Congress for management of byproduct material as defined in Section 11e.(2) of the AEA. Commenters cite to the framework in Section 275 of the AEA, which directs the EPA to establish standards for management of byproduct material and which gives the NRC sole authority over implementation and enforcement of the EPA's standards through its licensing process (one commenter cites Title 42 of the United States Code, Section 2022(d) rather than Section 275 of the AEA). Several commenters refer specifically to that section's statement that "no permit issued by the Administrator is required . . . for the processing, possession, transfer, or disposal of byproduct material, as defined in section 11e.(2) to this subsection." Another commenter suggests that the EPA is attempting to expand its role by improperly assuming or duplicating the NRC's responsibilities.

One commenter does not make these specific statutory references, but more generally criticizes the EPA for "grossly inefficient, dual regulation" that is "inconsistent with efficient regulatory practices" and goes against previous efforts by the two agencies to avoid such situations, as illustrated by the EPA's rescission of 40 CFR part 61, subparts I and T. The commenter suggests that Subpart W could also be rescinded, and notes that the EPA's separate rulemaking related to 40 CFR part 192 may be used to incorporate elements of Subpart W as needed.

We also received some comments in support of the proposal to remove the phrase "as determined by the Nuclear Regulatory Commission." One commenter believes this is a welcome clarification that the EPA is administering the NESHAP program. Another commenter notes that it is not unusual for an industry to be regulated under more than one statute or agency. A third commenter points out that this situation has existed for several

decades. A fourth commenter agrees and cites the EPA approvals under 40 CFR part 61, subpart A, as well as the division of responsibilities at the state level in Utah as they relate to the White Mesa Mill.

*Response:* The EPA disagrees that the change will be burdensome to licensees or create additional barriers to regulatory approval. We proposed this change to be consistent with the proposal to narrow the reference to the impoundment engineering and construction requirements. As explained in the preamble to the proposed rule, the requirements at 40 CFR 61.252(b) and (c) required compliance with 40 CFR 192.32(a) (79 FR 25406). However, we focus the Subpart W requirements on the impoundment design and construction requirements found specifically at 40 CFR 192.32(a)(1). The remainder of 40 CFR 192.32(a) goes beyond this limited scope by including requirements for ground-water detection monitoring systems and closure of operating impoundments. These other requirements, along with all of the part 192 standards, are implemented and enforced by the NRC through its licensing requirements for uranium recovery facilities at 10 CFR part 40, Appendix A. It is appropriate for compliance with those provisions to be solely determined by the NRC. However, when referenced in Subpart W, the requirements in 40 CFR 192.32(a)(1) would also be implemented and enforced by the EPA as the regulatory authority administering Subpart W under its CAA authority. Therefore, we revised 40 CFR 61.252(b) and (c) to specifically define which portions of 40 CFR 192.32(a) are applicable to Subpart W. Section 61.252(b) is re-numbered as 61.252(a)(2) and section 61.252(c) is incorporated into 61.252(a)(1) in the final rule.

The comments confirm that there is a misimpression that this reference to the NRC precluded the EPA from reviewing applications for compliance with 40 CFR 192.32(a)(1) in its pre-construction and modifications reviews under 40 CFR 61.07 and 61.08. That is an incorrect interpretation of the 1989 rule. To the contrary, in promulgating the 1989 rule, we stated "Mill operators will not be allowed to build any new mill tailings impoundment which does not meet this work practice standard. EPA will receive information on the construction of new impoundments through the requirements for EPA to approve of new construction under 40 CFR part 61, subpart A" (54 FR 51682). The referenced "work practice standard" includes the requirement for

conformance with 40 CFR 192.32(a). We are eliminating the reference to the NRC to clarify that the EPA is an approval authority for the impoundment engineering and construction provisions in 40 CFR 192.32(a)(1). This change will have no effect on the licensing requirements of the NRC or its regulatory authority under UMTRCA to implement the part 192 standards through its licenses.

Commenters' references to AEA Section 275 as limiting our authority are incorrect. The commenters have overlooked a salient point, which is that the Subpart W rulemaking is being undertaken pursuant to our CAA authority, not under the AEA. Another relevant provision in Section 275, 275e (42 U.S.C. 2022(e)), states: "Nothing in this Act applicable to byproduct material, as defined in section 11e.(2) of this Act, shall affect the authority of the Administrator under the Clean Air Act of 1970, as amended, or the Federal Water Pollution Control Act, as amended." The Federal Water Pollution Control Act is also known as the Clean Water Act.

Further, commenters who cited the prohibition on EPA permitting neglected to note the context for this provision and the specificity of the language regarding the standards of general application to be developed by the EPA. AEA section 275b.(2) reads as follows: "Such generally applicable standards promulgated pursuant to this subsection for nonradiological hazards shall provide for the protection of human health and the environment consistent with the standards required under subtitle C of the Solid Waste Disposal Act, as amended, which are applicable to such hazards: *Provided, however,* That no permit issued by the Administrator is required under this Act or the Solid Waste Disposal Act, as amended, for the processing, possession, transfer, or disposal of byproduct material, as defined in section 11e.(2) to this subsection" (emphasis in original). Thus, Congress required the EPA's standards to be consistent with standards applicable to nonradiological hazardous waste (subtitle C of the Solid Waste Disposal Act, better known as the Resource Conservation and Recovery Act, or RCRA) in lieu of the Agency exercising permitting authority under either the AEA or RCRA. The EPA is not contravening this restriction by exercising regulatory authority under the CAA. Responses to other comments on our legal authorities for this action may be found in Section IV.A.2.

Regarding the view of appropriate and efficient regulation, our action will not

have such far-reaching consequences. The EPA and the NRC have not examined the prospect of rescinding Subpart W. As with the rescission of 40 CFR part 61, subparts I and T, and in accordance with CAA section 112(d)(9), the EPA would need to determine that the NRC's regulatory program will protect public health with an ample margin of safety. The EPA's separate rulemaking under 40 CFR part 192 specifically addresses ground water protection at ISL facilities.

*Comment:* Several commenters addressed the definition of "uranium byproduct material or tailings" in Subpart W. Commenters generally raised the distinction between "tailings" and "byproduct material" under the AEA as germane to the scope of this rulemaking. One commenter suggests that the historical focus on conventional mill tailings impoundments (or "piles") is linked to the CAA, and that we are impermissibly re-defining non-tailings byproduct material as "tailings" as a means to address them under the CAA. Another commenter noted the following in reference to the AEA definition: "All tailings are byproduct material, but not all byproduct materials are tailings." A third commenter asks for clarification on how restoration fluids may be considered byproduct material. Several commenters suggested that we adopt the NRC's definition in 10 CFR 40.4 as a means to improve clarity and consistency.

Another commenter raised a question regarding wastes at uranium recovery facilities that are not derived from ores. The commenter stated that such wastes may derive from "alternate feed" materials that contain sufficient uranium to make processing worthwhile (e.g., tailings from other mineral extraction operations), or could include wastes placed directly into conventional impoundments because they are physically or chemically similar to the material already being managed.

*Response:* Although we received suggestions to adopt the AEA's and the NRC's definition of byproduct material, we did not propose to revise the definition of uranium byproduct material or tailings. CAA section 112(q) explicitly retains standards such as Subpart W that were in effect before the date of enactment of the CAA Amendments of 1990, so the existing definition of uranium byproduct material or tailings remains unless or until the EPA revises it. Because we did not propose to revise the definition of uranium byproduct material or tailings, we did not open it for comment. The EPA first defined the term "uranium byproduct material or tailings" in 1986

and has generally used the term "tailings" in Subpart W for simplicity. This rulemaking clarifies the scope of the EPA's term "uranium byproduct material or tailings" and provides reassurance that it is not in conflict with NRC's definitions. The following discussion is provided for informational purposes to further clarify this issue.

We note that the EPA has clear authority to promulgate definitions under the CAA as it deems appropriate and is not limited to the AEA's definition of "byproduct material" or the NRC's definition in 10 CFR 40.4. The EPA's definition identifies the scope of material covered by the Subpart W regulations and does not preempt the NRC's AEA authority. See Section IV.A.2 for more discussion of legal authorities as they relate to this issue.

The definition of "uranium byproduct material or tailings" in Subpart W, as it was promulgated in 1989 and not modified by this rule, establishes that Subpart W broadly addresses radon emissions from operating structures used to manage wastes produced during and following the concentration or extraction of uranium from ore processed primarily for its source material content. The EPA acknowledges that the definition of "uranium byproduct material or tailings," as originally promulgated in 1989, may not wholly conform with the common understanding of "tailings." However, the scope and applicability of Subpart W is determined by the regulatory definition of "uranium byproduct material or tailings," not the common understanding of tailings. Subpart W applies to the structures at uranium recovery facilities that are used to manage or contain "uranium byproduct material or tailings" during and following the processing of uranium ores. Common names for these structures may include, but are not limited to, impoundments, tailings impoundments, tailings piles, evaporation or holding ponds, and heap leach piles. However, the name itself is not important for determining whether Subpart W requirements apply to that structure; rather, applicability is based on what these structures contain. To clarify any potential confusion created by the Subpart W definition, any references to "uranium byproduct material" or "tailings" are now references to "uranium byproduct material or tailings." These changes reaffirm the scope of Subpart W and are not substantive.

The defined scope of materials subject to Subpart W becomes more meaningful when one considers the current

dominance of ISL in uranium recovery. At these sites, where conventional impoundments are not present, non-conventional impoundments managing uranium byproduct material or tailings are the most significant potential source of radon during operations. Although we do not generally expect non-conventional impoundments to be as large a source of potential emissions as conventional impoundments, non-conventional impoundments manage uranium byproduct material or tailings and emit or have the potential to emit sufficient radon that it is appropriate for the EPA to address them under Subpart W.

The designation of restoration fluids as uranium byproduct material or tailings is consistent with the approach taken by the NRC. See Staff Requirements Memorandum—SECY-99-013, “Recommendation on Ways to Improve the Efficiency of NRC Regulation at *In Situ* Leach Uranium Recovery Facilities,” July 26, 2000.

It is not necessary for us to explicitly address waste not resulting from the concentration or extraction of ores because Subpart W applies to impoundments, both conventional and non-conventional, that are used to manage uranium byproduct material or tailings. Such impoundments that also contain non-ore wastes continue to be subject to Subpart W. It is unlikely that an operator would construct impoundments for the sole purpose of managing wastes that do not derive from the processing of ores. As explained in Section IV.E.2, the purpose of Subpart W is to control radon emissions from sources containing uranium byproduct material or tailings at uranium recovery facilities. If an impoundment does not contain uranium byproduct material or tailings, it is not subject to the requirements of Subpart W. If construction of such impoundments is

planned, they can be identified and their status can be addressed during the construction application review under subpart A.

*Comment:* Commenters requested clarification regarding whether liquids in impoundments *contain* byproduct material or *are* byproduct material. One commenter asked us to clarify that solids *and* liquids in impoundments are byproduct material.

*Response:* Subpart W applies to conventional and non-conventional impoundments to the extent they are used to manage uranium byproduct material or tailings, with the primary concern being the potential to emit radon. The uranium byproduct material or tailings may be in solution or suspension in liquids that are discharged to these impoundments, or in sediments after settling out from the liquids.

**V. Summary of Environmental, Cost and Economic Impacts**

As discussed earlier, uranium recovery activities are carried out at several different types of facilities. We are revising Subpart W based on how uranium recovery facilities manage uranium byproduct materials during and after the processing of uranium ore at their particular facility. As discussed in Sections III and IV, we are establishing GACT-based requirements for three types of affected sources at uranium recovery facilities: (1) Conventional impoundments; (2) non-conventional impoundments; and (3) heap leach piles.

For purposes of analyzing the impacts of the final rule, we assumed that approximately five conventional milling facilities, 50 ISL facilities (although this is only a projection since only 12 are fully licensed) and one heap leach facility, each with at least one regulated impoundment, are subject to the final

Subpart W. The following sections present our estimates of the final rule’s air quality, cost and economic impacts. For more information, please refer to the Economic Impact Analysis (EIA) report that is included in the public docket for this final rule (EPA-HQ-OAR-2008-0218).

*A. What are the air quality impacts?*

The requirements in this final rule should eliminate or reduce radon emissions at all three types of affected sources. The GACT-based standards being established by this action are based on control technologies and management practices that have been used at uranium recovery facilities for the past twenty or more years. These standards will minimize the amount of radon that is released to the air by keeping the impoundments wet or covered with soil and/or by limiting the area of exposed uranium byproduct material or tailings.

*B. What are the cost and economic impacts?*

Table 5 presents a summary of the unit cost (per pound of U<sub>3</sub>O<sub>8</sub>) for implementing each GACT-based standard at each of the three types of uranium recovery facilities. Because the requirements for liners are not attributable to Subpart W, but are required by other regulations, the only costs attributable to this rulemaking are related to maintaining liquids in non-conventional impoundments. In addition to presenting the GACT costs individually, Table 5 presents the total unit cost to implement all relevant GACT-based standards at each type of facility. For example, the table shows that conventional mills will have both conventional impoundments and non-conventional impoundments, and will also be required to maintain saturation in the non-conventional impoundments.

TABLE 5—FINAL GACT STANDARDS COSTS PER POUND OF U<sub>3</sub>O<sub>8</sub>

	Unit cost (\$/lb U <sub>3</sub> O <sub>8</sub> )		
	Conventional mills	ISL facilities	Heap leach
GACT—Double Liners for Conventional Impoundments *	\$1.04	.....	.....
GACT—Double Liners for Non-conventional Impoundments *	1.04	\$3.07	\$0.22
GACT—Maintaining Non-conventional Impoundment Sediments 100% Saturated	0.015	0.026	0.0013
GACT—Liners for Heap Leach Piles *	.....	.....	2.01
GACTs—Total for All Four	2.09	3.09	2.24
Baseline Facility Costs** (EIA Section 6.2)	55.18	51.31	45.06
Baseline Facility Costs***	51.56	52.49	46.08

\* Liners required by 40 CFR part 192.

\*\* Based on Price of U<sub>3</sub>O<sub>8</sub> at \$55/lb.

\*\*\* Based on Price of U<sub>3</sub>O<sub>8</sub> at \$65/lb (used in proposed rule).

A reference facility for each type of uranium recovery facility is developed and described in Section 6.2 of the EIA, including the base cost estimate to construct and operate each of the three types of reference facilities. For comparison purposes, the unit cost (per pound of  $U_3O_8$ ) of the three uranium recovery reference facilities is presented at the bottom of Table 5. In developing the baseline cost, it was assumed that the price of  $U_3O_8$  is \$55 per pound. At that price, baseline facility costs increase somewhat for the conventional mill because the cost of financing (*i.e.*, interest) also increases as revenues are lower. The baseline cost for a conventional mill actually exceeds the \$55/lb, which suggests that the mill cannot operate profitably. Baseline costs at \$65 per pound, which was used to support the proposed rule, are also shown for comparison. This illustrates the sensitivity of facility cost to market price, which is more significant than the cost of implementing the GACT-based standards.

Based on the information in Table 5, the four GACT-based standards represent about 4%, 6%, and 5% of the baseline cost (per pound of  $U_3O_8$ ) at conventional, ISL, and heap leach uranium recovery facilities, respectively. The baseline costs were estimated using recently published cost data for actual uranium recovery facilities. For the model conventional mill, we used data from the recently licensed new mill at the Piñon Ridge project in Colorado. For the model ISL facility, we used data from two proposed new facilities: (1) The Centennial Uranium project in Colorado; and (2) the Dewey-Burdock project in South Dakota. The Centennial project is expected to have a 14- to 15-year production period, which is a long duration for an ISL facility, while the Dewey-Burdock project is expected to have a shorter production period of about 9 years, which is more representative of ISL facilities. For the heap leach facility, we used data from the proposed Sheep Mountain project in Wyoming.

Baseline costs for conventional impoundment liner construction<sup>25</sup> will

<sup>25</sup> These liner systems (conventional, non-conventional and heap leach piles) are already required by 40 CFR 192.32(a)(1), which, as explained above, are requirements promulgated by the EPA under UMTRCA that are incorporated into NRC regulations and implemented and enforced by the NRC through its licensing requirements. Therefore, we are not placing any additional liner requirements on facilities or requiring them to incur any additional costs to build their conventional or non-conventional impoundments or heap leach piles above and beyond what an owner or operator of these impoundments must already incur to

remain the same, since the final rule does not impose additional requirements. Liners meeting the requirements at 40 CFR 192.32(a)(1) are already mandated by other regulations and were mandated by the 1989 rule and, therefore, are built into the baseline cost estimate. As a result, there are no costs (or benefits) resulting from the inclusion of these requirements in the final rule.

The average cost to construct one of these impoundments is \$13.8 million. We estimate that this cost is less than 2% of the total baseline costs to construct and operate a conventional mill, per pound of  $U_3O_8$  produced.

We have estimated that for an average 80-acre non-conventional impoundment the average cost of construction of an impoundment is \$24.7 million. Requiring impoundments to comply with the liner requirements in 40 CFR 192.32(a)(1) will contain the uranium byproduct material and reduce the potential for ground water contamination. The only economic impact attributable to the final rule is the cost of complying with the new requirement to maintain liquids such that solids in the non-conventional impoundments are not visible above the liquid level during operation and standby. As explained in Section IV.B.3. of this preamble, as long as solid materials are maintained in a saturated state in the non-conventional impoundments the effective radon emissions from the ponds are reduced by approximately 95%. In order to maintain a liquid surface above the sediments within a pond, it is necessary to replace the water that is evaporated from the pond. Depending on the source of water chosen, we estimate that this requirement will cost owners or operators of non-conventional impoundments between \$2,909 and \$37,527 per year.<sup>26</sup> This value also varies according to the size of the non-conventional impoundment, up to 80 acres, and the location of the impoundment. Evaporation rates vary by geographic location. The requirement to maintain a liquid surface above solid materials in the ponds is estimated to

obtain an NRC license. Therefore, there are no projected costs (or benefits) beyond the baseline resulting from the inclusion of these requirements in Subpart W.

<sup>26</sup> These figures are higher than those estimated for the proposed rule. We received information during the comment period that resulted in an increase in the estimated cost of obtaining makeup water, so the final rule requirement of 100% saturation is still lower than the proposed requirement to maintain one meter of liquid, using the same base water costs.

cost less than \$0.03 per pound of uranium produced.

Designing and constructing heap leach piles to meet the requirements at 40 CFR 192.32(a)(1) will minimize the potential for leakage of uranium enriched lixiviant into the ground water. Specifically, this will require that a double liner, with drainage collection capabilities, be provided under heap leach piles. Baseline costs for heap leach pile liner construction will remain the same, since the final rule does not impose additional requirements. Liners meeting the requirements at 40 CFR 192.32(a)(1) are already mandated by other regulations and, therefore, built into the baseline cost estimate. Therefore there are consequently no costs (or benefits) resulting from the inclusion of these requirements in Subpart W. Baseline costs for construction will be essentially the same as for conventional impoundments. Since the liner systems are equivalent to the systems used for conventional and non-conventional impoundments, we have been able to estimate the average costs associated with the construction of heap leach pile impoundments that meet the liner requirements we are proposing, and compare them to the costs associated with the total production of uranium produced by the facility. The average cost of constructing such an impoundment is estimated to be approximately \$12.6 million. The costs of constructing this type of liner system are less than 5% of the estimated total baseline costs of a heap leach facility.

In summary, we estimate that for conventional impoundments there will be no additional costs incurred through this proposed rule. For non-conventional impoundments we estimate that the additional costs incurred by this proposed rule will be to maintain a layer of liquid above solid materials in each non-conventional impoundment, and we have estimated those costs between approximately \$2,909 and \$37,527 per year, which represents less than \$0.03 per pound of  $U_3O_8$  produced. For heap leach piles, no additional costs will be incurred.

### C. What are the non-air environmental impacts?

Water quality will be maintained by implementation of this final rule. This final rule does contain requirements (by reference) related to water discharges and spill containment. In fact, the liner requirements cross referenced at 40 CFR 192.32(a)(1) will significantly decrease the possibility of contaminated liquids leaking from impoundments into ground water (which can be a



significant source of drinking water). Section 192.32(a)(1) includes a cross-reference to the surface impoundment design and construction requirements of hazardous waste surface impoundments regulated under RCRA, found at 40 CFR 264.221. Those requirements state that the impoundment shall be designed, constructed and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil or ground water or surface water at any time during the active life of the impoundment. There are other requirements in 40 CFR 264.221 for the design and operation of the impoundment, and these include construction specifications, slope requirements, sump and liquid removal requirements. These liner systems for conventional and non-conventional impoundments and heap leach piles are already required by 40 CFR 192.32(a)(1), which, as explained above, are requirements promulgated by the EPA under UMTRCA that are incorporated into NRC regulations and implemented and enforced by the NRC through their licensing requirements. Therefore, we are not placing any additional liner requirements on facilities or requiring them to incur any additional costs to build their conventional or non-conventional impoundments or heap leach piles above and beyond what an owner or operator of these impoundments must already incur to obtain an NRC license.

Including a double liner in the design of all onsite impoundments that would contain uranium byproduct material or tailings will reduce the potential for groundwater contamination. Although the amount of the potential reduction is not quantifiable, it is important to take this into consideration due to the significant use of ground water as a source of drinking water.

## VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to OMB for review. The Executive Order (E.O.) defines “significant regulatory action” as one that is likely to result in a rule that may “raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.” Any

changes made in response to OMB recommendations have been documented in the docket for this action. The EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, “Technical and Regulatory Support to Develop a Rulemaking to Modify the NESHAP Subpart W Standard for Radon Emissions from Operating Mill Tailings (Background Information Document and Economic Impact Analysis),” Docket No. EPA-HQ-OAR-2008-0218, is available in the docket and summarized in Section V of this preamble. This action is not a significant economic action.

### *B. Paperwork Reduction Act (PRA)*

The information collection requirements in this rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document prepared by the EPA has been assigned EPA ICR number 2464.02. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information to be collected for the rule is based on the requirements of the CAA. Section 114 authorizes the Administrator of the EPA to require any person who owns or operates any emission source or who is subject to any requirements of the Act to:

- Establish and maintain records
- Make reports, install, use, and maintain monitoring equipment or method
- Sample emissions in accordance with EPA-prescribed locations, intervals and methods
- Provide information as may be requested

EPA’s regional offices use the information collected to ensure that public health continues to be protected from the hazards of radionuclides by compliance with health based standards and/or GACT.

The rule requires the owner or operator of a uranium recovery facility to maintain records that confirm that the conventional impoundment(s), non-conventional impoundment(s) and heap leach pile(s) meet the requirements in § 192.32(a)(1). Included in these records are the results of liner compatibility tests and documentation that a layer of liquid above solid materials has been maintained in non-conventional impoundments. This documentation should be sufficient to allow an independent auditor (such as an EPA

inspector) to verify the accuracy of the determination made concerning the facility’s compliance with the standard. These records must be kept at the mill or facility for the operational life of the facility and, upon request, be made available for inspection by the Administrator, or his/her authorized representative. The rule requires the owners or operators of operating non-conventional impoundments to submit digital photographs taken during the compliance inspections required in section 61.252(b). The recordkeeping requirements require only the specific information needed to determine compliance. We have taken this step to minimize the reporting requirements for small business facilities.

The annual monitoring and recordkeeping burden to affected sources for this collection (averaged over the first three years after the effective date of the final rule) is estimated to be 6,693 hours with a total annual cost of \$336,950 for the requirements related to documenting the liquid level in non-conventional impoundments, and a one-time expenditure of 460 hours and \$32,890 to maintain records of impoundment design and construction. This estimate includes a total capital and start-up cost component annualized over the facility’s expected useful life and a purchase of services component. We estimate that this total burden will be spread over 23 facilities that will be required to keep records.

Burden is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

### *C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses whose company has less than 250 employees and is primarily engaged in leaching or beneficiation of uranium, radium or vanadium ores as defined by NAICS code 212291.

The EPA has determined that small entities subject to the requirements of

this action are approximately 18 uranium recovery facilities that are currently operating or plan to operate in the future. The Agency has determined that the ten small businesses that own these facilities may experience an impact of less than 1% of total annual production costs, or less than \$0.03 per pound of uranium produced. Details of this analysis are presented in Section 6 of the BID/EIA prepared to support this rulemaking (Docket No. EPA-HQ-OAR-2008-0218).

#### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The final rule imposes no enforceable duty on any state, local or tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments nor does it impose obligations upon them.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. None of the facilities subject to this action are owned and operated by State governments and nothing in the final rule will supersede State regulations. Thus, E.O. 13132 does not apply to this final rule.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. The action imposes requirements on owners and operators of specified area sources and not tribal governments. Thus, Executive Order 13175 does not apply to this action.

The EPA notes, however, that several tribes or tribal groups expressed interest in this rulemaking due to the proximity of some of the facilities regulated under Subpart W to tribal lands. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA consulted with tribal officials

of the Ute Mountain Ute Tribe during development of this action. A summary of that consultation is provided in Docket No. EPA-HQ-OAR-2008-0218-0120.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. This action's health and risk assessments are contained in Section IV.B.2 of this preamble and in the Background Information Document prepared to support this action (Docket No. EPA-HQ-OAR-2008-0218). The updated risk assessment described in Section IV.B.2 incorporated the risk coefficients from Federal Guidance Report (FGR) No. 13, "Cancer Risk Coefficients for Environmental Exposure to Radionuclides," which includes age-averaged factors to convert radionuclide exposure (intake) to health risk. FGR 13 was developed subsequent to the risk assessment conducted to support the 1989 rulemaking, which relied upon factors applicable to adults. FGR 13 is undergoing revision.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This final rule will not adversely affect productivity, competition, or prices in the energy sector.

#### *I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards. The rule retains requirements for radon monitoring using Method 115 that were promulgated in 1989.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in Section IV.B.2 of this preamble and the Background Information Document prepared to

support this action (Docket No. EPA-HQ-OAR-2008-0218).

#### *K. Congressional Review Act (CRA)*

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

#### **List of Subjects in 40 CFR Part 61**

Environmental protection, Air pollution control, Hazardous substances, Radon, Tailings, Byproduct, Uranium, Reporting and recordkeeping requirements.

Dated: December 20, 2016.

**Gina McCarthy**,  
Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends title 40, Chapter I of the Code of Federal Regulations as follows:

#### **PART 61—NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS**

■ 1. The authority citation for part 61 continues to read as follows:

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

#### **Subpart W—National Emission Standards for Radon Emissions From Operating Mill Tailings**

■ 2. Section 61.251 is amended by revising paragraphs (b) through (f) and adding paragraphs (h) through (o) to read as follows:

##### **§ 61.251 Definitions.**

\* \* \* \* \*

(b) *Continuous disposal* means a method of uranium byproduct material or tailings management and disposal in which uranium byproduct material or tailings are dewatered by mechanical methods immediately after generation. The dried uranium byproduct material or tailings are then placed in trenches or other disposal areas and immediately covered to limit emissions consistent with applicable Federal standards.

(c) *Dewatered* means to remove the water from recently produced uranium byproduct material or tailings by mechanical or evaporative methods such that the water content of the uranium byproduct material or tailings does not exceed 30 percent by weight.

(d) *Existing conventional impoundment* means any conventional uranium byproduct material or tailings impoundment which is licensed to accept additional uranium byproduct material or tailings and is in existence on December 15, 1989.

(e) *Operation*. Operation means that an impoundment is being used for the continued placement of uranium byproduct material or tailings or is in standby status for such placement. An impoundment is in operation from the day that uranium byproduct material or tailings are first placed in the impoundment until the day that final closure begins.

(f) *Phased disposal* means a method of uranium byproduct material or tailings management and disposal which uses lined impoundments which are filled and then immediately dried and covered to meet all applicable Federal standards.

\* \* \* \* \*

(h) *Conventional impoundment*. A conventional impoundment is a permanent structure located at any uranium recovery facility which contains mostly solid uranium byproduct material or tailings from the extraction of uranium from uranium ore. These impoundments are left in place at facility closure.

(i) *Non-conventional impoundment*. A non-conventional impoundment is used for managing liquids from uranium recovery operations and contains uranium byproduct material or tailings suspended in and/or covered by liquids. These structures are commonly known as holding ponds or evaporation ponds and can be located at any uranium recovery facility. They are typically not permanent structures unless they transition to become used as conventional impoundments. Impoundments constructed for the purpose of managing liquids from closure or remediation activities (e.g., contaminated groundwater), and which are used solely for that purpose, are not subject to the requirements of this subpart.

(j) *Heap leach pile*. A heap leach pile is a pile of uranium ore placed on an engineered structure and stacked so as to allow uranium to be dissolved and removed by leaching liquids.

(k) *Standby*. Standby means the period of time that an impoundment is not accepting uranium byproduct material or tailings but has not yet entered final closure.

(l) *Uranium recovery facility*. A uranium recovery facility means a facility licensed by the NRC or an NRC Agreement State to manage uranium byproduct material or tailings during and following the processing of uranium ores. Common names for these facilities are a conventional uranium mill, an in-situ leach (or recovery) facility and a heap leach facility or pile.

(m) *Heap leach pile operational life*. The operational life of a heap leach pile

means the time period from the first time that lixiviant is placed on the heap leach pile until the time the final rinse is completed.

(n) *Final closure* means the period during which an impoundment or heap leach pile is being managed in accordance with the milestones and requirements in an approved reclamation plan. Final closure for the impoundment or heap leach pile begins when the owner or operator provides written notice to the Administrator and to the Nuclear Regulatory Commission or applicable NRC Agreement State that:

(1) A conventional impoundment is no longer receiving uranium byproduct material or tailings, is no longer on standby for such receipt and is being managed under an approved reclamation plan for that impoundment or facility closure plan; or

(2) A non-conventional impoundment is no longer required for evaporation or holding purposes, is no longer on standby for such purposes and is being managed under an approved reclamation plan for that impoundment or facility closure plan; or

(3) A heap leach pile has concluded its operational life and is being managed under an approved reclamation plan for that pile or facility closure plan.

(o) *Reclamation plan* means the plan detailing activities and milestones to accomplish reclamation of impoundments or piles containing uranium byproduct material or tailings. Activities and milestones to be addressed include, but are not limited to, dewatering and contouring of conventional impoundments and heap leach piles, and removal and disposal of non-conventional impoundments. A reclamation plan prepared and approved in accordance with 10 CFR part 40, Appendix A is considered a reclamation plan in this subpart.

■ 3. Section 61.252 is revised to read as follows:

**§ 61.252 Standard.**

(a) Each owner or operator of a conventional impoundment shall comply with the following requirements:

(1) Radon-222 emissions to the ambient air from an existing conventional impoundment shall not exceed 20 pCi/(m<sup>2</sup>-sec) (1.9 pCi/(ft<sup>2</sup>-sec)) of radon-222 and all owners or operators shall comply with the provisions of 40 CFR 192.32(a)(1) in the operation of the impoundment notwithstanding the exemption for existing impoundments in 40 CFR 192.32(a)(1).

(2) After December 15, 1989, no new conventional impoundment may be

built unless it is designed, constructed and operated to meet one of the two following management practices:

(i) Phased disposal in lined impoundments that are no more than 40 acres in area and comply with the requirements of 40 CFR 192.32(a)(1). The owner or operator shall have no more than two conventional impoundments, including existing conventional impoundments, in operation at any one time.

(ii) Continuous disposal such that uranium byproduct material or tailings are dewatered and immediately disposed with no more than 10 acres uncovered at any time and shall comply with the requirements of 40 CFR 192.32(a)(1).

(b) Each owner or operator of a non-conventional impoundment shall comply with the following requirements: Non-conventional impoundments shall meet the requirements of 40 CFR 192.32(a)(1). During operation and until final closure begins, the liquid level in the impoundment shall be maintained so that solid materials in the impoundment are not visible above the liquid surface, verified by daily inspections documented through notations and by digital photographic evidence collected at least weekly. Should inspection reveal that solid materials in the impoundment are visible above the liquid surface, the owner or operator must correct the situation within seven days, or other such time as specified by the Administrator.

(c) Each owner or operator of a heap leach pile shall comply with the following requirements: Heap leach piles that have completed their operating life but have not yet entered final closure shall be managed in compliance with the phased disposal management practice in paragraph (a)(2)(i) of this section. Heap leach piles shall be constructed in lined impoundments that are no more than 40 acres in area and shall comply with the requirements of 40 CFR 192.32(a)(1). The owner or operator shall have no more than two heap leach piles, including existing heap leach piles, subject to this subpart at any one time.

■ 4. Section 61.255 is revised to read as follows:

**§ 61.255 Recordkeeping requirements.**

(a) The owner or operator of any uranium recovery facility must maintain records that confirm that the conventional impoundment(s), non-conventional impoundment(s) and heap leach pile(s) subject to this subpart at the facility meet the requirements in 40 CFR 192.32(a)(1). These records shall

include, but not be limited to, the results of liner compatibility tests.

(b) The owner or operator of any uranium recovery facility with non-conventional impoundments must maintain written records from daily inspections and other records confirming that any sediments have remained saturated in the non-conventional impoundments at the facility. Periodic digital photographic evidence, with embedded date stamp and other identifying metadata, shall be collected no less frequently than weekly to demonstrate compliance with the requirements of § 61.252(b). Should inspection reveal that a non-conventional impoundment is not in compliance with the requirements of

§ 61.252(b), the owner or operator shall collect photographic evidence before and after the non-compliance is corrected.

(c) The records required in paragraphs (a) and (b) in this section must be kept at the uranium recovery facility for the operational life of the facility and must be made available for inspection by the Administrator, or his authorized representative.

(1) Digital photographs taken to demonstrate compliance with the requirements of § 61.252(c) shall be submitted electronically using the Subpart W Impoundment Photographic Reporting (SWIPR) system that is accessed through EPA's Central Data

Exchange (CDX) (*cdx.epa.gov*) at least monthly.

(i) Owners and operators must also submit information identifying the facility and facility location, the name or other designation of each impoundment, and the date and time of each photograph.

(ii) If the reporting form specific to this subpart is not available in SWIPR, the owner or operator must retain the digital photographs at the facility and provide them to the EPA or authorized State upon request, with the supporting information required in paragraph (c)(1)(i) of this section.

(2) [Reserved]

[FR Doc. 2016-31425 Filed 1-13-17; 8:45 am]

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Part IV

## Environmental Protection Agency

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40 CFR Part 51

Revisions to the Guideline on Air Quality Models: Enhancements to the AERMOD Dispersion Modeling System and Incorporation of Approaches To Address Ozone and Fine Particulate Matter; Final Rule

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 51

[EPA-HQ-OAR-2015-0310; FRL-9956-23-OAR]

RIN 2060-AS54

### Revisions to the Guideline on Air Quality Models: Enhancements to the AERMOD Dispersion Modeling System and Incorporation of Approaches To Address Ozone and Fine Particulate Matter

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** In this action, the Environmental Protection Agency (EPA) promulgates revisions to the *Guideline on Air Quality Models* (“*Guideline*”). The *Guideline* provides EPA’s preferred models and other recommended techniques, as well as guidance for their use in estimating ambient concentrations of air pollutants. It is incorporated into the EPA’s regulations, satisfying a requirement under the Clean Air Act (CAA) for the EPA to specify with reasonable particularity models to be used in the Prevention of Significant Deterioration (PSD) program. This action includes enhancements to the formulation and application of the EPA’s preferred near-field dispersion modeling system, AERMOD (American Meteorological Society (AMS)/EPA Regulatory Model), and the incorporation of a tiered demonstration approach to address the secondary chemical formation of ozone and fine particulate matter (PM<sub>2.5</sub>) associated with precursor emissions from single sources. The EPA is changing the preferred status of and removing several air quality models from appendix A of the *Guideline*. The EPA is also making various editorial changes to update and reorganize information throughout the *Guideline* to streamline the compliance assessment process.

**DATES:** This rule is effective February 16, 2017. For all regulatory applications covered under the *Guideline*, except for transportation conformity, the changes to the appendix A preferred models and revisions to the requirements and recommendations of the *Guideline* must be integrated into the regulatory processes of respective reviewing authorities and followed by applicants by no later than January 17, 2018. During the 1-year period following promulgation, protocols for modeling analyses based on the 2005 version of the *Guideline*, which are submitted in a

timely manner, may be approved at the discretion of the appropriate reviewing authority.

This final rule also starts a 3-year transition period that ends on January 17, 2020 for transportation conformity purposes. Any refined analyses that are started before the end of this 3-year period, with a preferred appendix A model based on the 2005 version of the *Guideline*, can be completed after the end of the transition period, similar to implementation of the transportation conformity grace period for new emissions models. See the discussion in section IV.A.4 of this preamble for details on how this transition period will be implemented.

All applicants are encouraged to consult with their respective reviewing authority as soon as possible to assure acceptance of their modeling protocols and/or modeling demonstration during either of these periods.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2015-0310. All documents in the docket are listed on the <https://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. George M. Bridgers, Air Quality Assessment Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C439-01, Research Triangle Park, NC 27711; telephone: (919) 541-5563; fax: (919) 541-0044; email: [Bridgers.George@epa.gov](mailto:Bridgers.George@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

The following topics are discussed in this preamble:

- I. General Information
  - A. Does this action apply to me?
  - B. Where can I get a copy of this rule and related information?
  - C. Judicial Review
  - D. List of Acronyms
- II. Background
- III. The Tenth and Eleventh Conferences on Air Quality Modeling and Public Hearing
- IV. Discussion of Public Comments on the Proposed Changes to the Guideline
  - A. Final Action
    1. Clarifications To Distinguish Requirements From Recommendations

2. Updates to EPA’s AERMOD Modeling System
3. Status of AERSCREEN
4. Status of CALINE3 Models
5. Addressing Single-Source Impacts on Ozone and Secondary PM<sub>2.5</sub>
6. Status of CALPUFF and Assessing Long-Range Transport for PSD Increments and Regional Haze
7. Role of EPA’s Model Clearinghouse (MCH)
8. Updates to Modeling Procedures for Cumulative Impact Analysis
9. Updates on Use of Meteorological Input Data for Regulatory Dispersion Modeling
- B. Final Editorial Changes
  1. Preface
  2. Section 1
  3. Section 2
  4. Section 3
  5. Section 4
  6. Section 5
  7. Section 6
  8. Section 7
  9. Section 8
  10. Section 9
  11. Section 10
  12. Section 11
  13. Section 12
  14. Appendix A to the *Guideline*
- V. Statutory and Executive Order Reviews
  - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  - B. Paperwork Reduction Act (PRA)
  - C. Regulatory Flexibility Act (RFA)
  - D. Unfunded Mandates Reform Act (UMRA)
  - E. Executive Order 13132: Federalism
  - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  - G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
  - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  - I. National Technology Transfer and Advancement Act
  - J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
  - K. Congressional Review Act (CRA)

#### I. General Information

##### A. Does this action apply to me?

This action applies to federal, state, territorial, local, and tribal air quality management agencies that conduct air quality modeling as part of State Implementation Plan (SIP) submittals and revisions, New Source Review (NSR) permitting (including new or modifying industrial sources under Prevention of Significant Deterioration (PSD)), conformity, and other air quality assessments required under EPA regulation. Categories and entities potentially regulated by this action include:

Category	NAICS <sup>a</sup> code
Federal/state/territorial/local/tribal government .....	924110

<sup>a</sup>North American Industry Classification System.

### B. Where can I get a copy of this rule and related information?

In addition to being available in the docket, electronic copies of the rule and related materials will also be available on the Worldwide Web (WWW) through the EPA's Support Center for Regulatory Atmospheric Modeling (SCRAM) Web site at <https://www.epa.gov/scram>.

### C. Judicial Review

This final rule is nationally applicable, as it revises the *Guideline on Air Quality Models*, 40 CFR part 51, appendix W. Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by March 20, 2017. Moreover, under section 307(b)(2) of the CAA, the requirements established by this action may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements. This rule is also subject to section 307(d) of the CAA.

### D. List of Acronyms

AEDT Aviation Environmental Design Tool  
 AERMET Meteorological data preprocessor for AERMOD  
 AERMINUTE Pre-processor to AERMET to read 1-minute ASOS data to calculate hourly average winds for input into AERMET  
 AERMOD American Meteorological Society (AMS)/EPA Regulatory Model  
 AERSCREEN Program to run AERMOD in screening mode  
 AERSURFACE Land cover data tool in AERMET  
 AQRV Air Quality Related Value  
 AQS Air Quality System  
 ARM Ambient Ratio Method  
 ARM2 Ambient Ratio Method 2  
 ASOS Automated Surface Observing Stations  
 ASTM American Society for Testing and Materials  
 B<sub>o</sub> Bowen ratio  
 BART Best available retrofit technology  
 BID Buoyancy-induced dispersion  
 BLP Buoyant Line and Point Source model  
 BOEM Bureau of Ocean Energy Management  
 BPIPMM Building Profile Input Program for PRIME  
 BUKLRN Bulk Richardson Number  
 CAA Clean Air Act  
 CAL3QHC Screening version of the CALINE3 model  
 CAL3QHCR Refined version of the CALINE3 model

CALINE3 California LINE Source Dispersion Model  
 CALMPRO Calms Processor  
 CALPUFF California Puff model  
 CALTRANS99 California Department of Transportation Highway 99 Tracer Experiment  
 CAMx Comprehensive Air Quality Model with Extensions  
 CFR Code of Federal Regulations  
 CMAQ Community Multiscale Air Quality  
 CO Carbon monoxide  
 CTDMPLUS Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations  
 CTSCREEN Screening version of CTDMPLUS  
 CTM Chemical transport model  
 dθ/dz Vertical potential temperature gradient  
 DT Temperature difference  
 EDMS Emissions and Dispersion Modeling System  
 EPA Environmental Protection Agency  
 FAA Federal Aviation Administration  
 FLAG Federal Land Managers' Air Quality Related Values Work Group Phase I Report  
 FLM Federal Land Manager  
 GEP Good engineering practice  
 GUI Graphical user interface  
 IBL Inhomogeneous boundary layer  
 ISC Industrial Source Complex model  
 IWAQM Interagency Workgroup on Air Quality Modeling  
 km kilometer  
 L Monin-Obukhov length  
 m meter  
 m/s meter per second  
 MAKEMET Program that generates a site-specific matrix of meteorological conditions for input to AERMOD  
 MAR Minimum ambient ratio  
 MCH Model Clearinghouse  
 MCHISRS Model Clearinghouse Information Storage and Retrieval System  
 MERPs Model Emissions Rates for Precursors  
 METPRO Meteorological Processor for dispersion models  
 MM5 Mesoscale Model 5  
 MMIF Mesoscale Model Interface program  
 MPRM Meteorological Processor for Regulatory Models  
 NAAQS National Ambient Air Quality Standards  
 NCEI National Centers for Environmental Information  
 NH<sub>3</sub> Ammonia  
 NO Nitric oxide  
 NOAA National Oceanic and Atmospheric Administration  
 NO<sub>x</sub> Nitrogen oxides  
 NO<sub>2</sub> Nitrogen dioxide  
 NSR New Source Review  
 NTI National Technical Information Service  
 NWS National Weather Service  
 OCD Offshore and Coastal Dispersion Model  
 OCS Outer Continental Shelf  
 OCSLA Outer Continental Shelf Lands Act  
 OLM Ozone Limiting Method  
 PCRAMMET Meteorological Processor for dispersion models  
 P-G stability Pasquill-Gifford stability  
 PM<sub>2.5</sub> Particles less than or equal to 2.5 micrometers in diameter

PM<sub>10</sub> Particles less than or equal to 10 micrometers in diameter  
 PRIME Plume Rise Model Enhancements algorithm  
 PSD Prevention of Significant Deterioration  
 PVMRM Plume Volume Molar Ratio Method  
 r Albedo  
 RHC Robust Highest Concentration  
 RLIN Research LINE source model for near-surface releases  
 SCICHEM Second-order Closure Integrated Puff Model  
 SCRAM Support Center for Regulatory Atmospheric Modeling  
 SCREEN3 A single source Gaussian plume model which provides maximum ground-level concentrations for point, area, flare, and volume sources  
 SDM Shoreline Dispersion Model  
 SILs Significant impact levels  
 SIP State Implementation Plan  
 SMAT Software for Model Attainment Test  
 SO<sub>2</sub> Sulfur dioxide  
 SRDT Solar radiation/delta-T method  
 TSD Technical support document  
 u Values for wind speed  
 u\* Surface friction velocity  
 VOC Volatile organic compound  
 w\* Convective velocity scale  
 WRF Weather Research and Forecasting model  
 z<sub>i</sub> Mixing height  
 Z<sub>o</sub> Surface roughness  
 Z<sub>ic</sub> Convective mixing height  
 Z<sub>im</sub> Mechanical mixing height  
 σ<sub>v</sub>, σ<sub>w</sub> Horizontal and vertical wind speeds

## II. Background

The *Guideline* is used by the EPA, other federal, state, territorial, local, and tribal air quality agencies, and industry to prepare and review new or modified source permits, SIP submittals or revisions, conformity, and other air quality assessments required under the CAA and EPA regulations. The *Guideline* serves as a means by which national consistency is maintained in air quality analyses for regulatory activities under 40 CFR (Code of Federal Regulations) 51.112, 51.117, 51.150, 51.160, 51.165, 51.166, 52.21, 93.116, 93.123, and 93.150.

The EPA originally published the *Guideline* in April 1978 (EPA-450/2-78-027), and it was incorporated by reference in the regulations for the PSD program in June 1978. The EPA revised the *Guideline* in 1986 (51 FR 32176), and updated it with supplement A in 1987 (53 FR 32081), supplement B in July 1993 (58 FR 38816), and supplement C in August 1995 (60 FR 40465). The EPA published the *Guideline* as appendix W to 40 CFR part 51 when the EPA issued supplement B. The EPA republished the *Guideline* in August 1996 (61 FR 41838) to adopt the CFR system for labeling paragraphs. Subsequently, the EPA revised the *Guideline* on April 15, 2003 (68 FR



18440), to adopt CALPUFF as the preferred model for long-range transport of emissions from 50 to several hundred kilometers (km) and to make various editorial changes to update and reorganize information and remove obsolete models. The EPA further revised the *Guideline* on November 9, 2005 (70 FR 68218), to adopt AERMOD as the preferred model for near-field dispersion of emissions for distances up to 50 km. The publication and incorporation of the *Guideline* into the EPA's PSD regulations satisfies the requirement under CAA section 165(e)(3) for the EPA to promulgate regulations that specify with reasonable particularity models to be used under specified sets of conditions for purposes of the PSD program.

On July 29, 2015, we proposed revisions to the *Guideline* in the **Federal Register** (80 FR 45340). The proposed revisions to the *Guideline* and preferred models are based upon stakeholder input received during the Tenth Conference on Air Quality Modeling. These proposed revisions were presented at the Eleventh Conference on Air Quality Modeling that included the public hearing for the proposed action. The conferences and public hearing are briefly described in section III of this preamble.

Section IV provides a brief discussion of comments received and our responses that support the changes to the *Guideline* being finalized through this action. A more comprehensive discussion of the public comments received and our responses are provided in the Response to Comments document that is included in the docket for this action.

### III. The Tenth and Eleventh Conferences on Air Quality Modeling and Public Hearing

To inform the development of our proposed revisions to the *Guideline* and in compliance with CAA section 320, we held the Tenth Conference on Air Quality Modeling in March 2012. The conference addressed updates on: The regulatory status and future development of AERMOD and CALPUFF, review of the Mesoscale Model Interface (MMIF) prognostic meteorological data processing tool for dispersion models, draft modeling guidance for compliance demonstrations of the PM<sub>2.5</sub> National Ambient Air Quality Standards (NAAQS), modeling for compliance demonstration of the 1-hour nitrogen dioxide (NO<sub>2</sub>) and sulfur dioxide (SO<sub>2</sub>) NAAQS, and new and emerging models/techniques for future consideration under the *Guideline* to

address single-source modeling for ozone and secondary PM<sub>2.5</sub>, as well as long-range transport and chemistry. Based on comments received from stakeholders at the Tenth Modeling Conference, "Phase 3" of the Interagency Workgroup on Air Quality Modeling (IWAQM) was formalized in June 2013 to provide additional guidance for modeling single-source impacts on secondarily formed pollutants (e.g., ozone and PM<sub>2.5</sub>) in the near-field and for long-range transport. A transcript of the conference proceedings and a summary of the public comments received are available in the docket for the Tenth Modeling Conference.<sup>1</sup> Additionally, all of the material associated with this conference are available on the EPA's SCRAM Web site at <https://www3.epa.gov/ttn/scram/10thmodconf.htm>.

The Eleventh Conference on Air Quality Modeling was held August 12–13, 2015, in continuing compliance with CAA section 320. The Eleventh Modeling Conference included the public hearing for this action. The conference began with a thorough overview of the proposed revisions to the *Guideline*, including presentations from EPA staff on the formulation updates to the preferred models and the research and technical evaluations that support these and other revisions. Specifically, there were presentations summarizing the proposed updates to the AERMOD modeling system, replacement of CALINE3 with AERMOD for modeling of mobile sources, incorporation of prognostic meteorological data for use in dispersion modeling, the proposed screening approach for long-range transport for NAAQS and PSD increments assessments with use of CALPUFF as a screening technique rather than an EPA-preferred model, the proposed 2-tiered screening approach to address ozone and PM<sub>2.5</sub> in PSD compliance demonstrations, the status and role of the Model Clearinghouse, and updates to procedures for single-source and cumulative modeling analyses (e.g., modeling domain, source input data, background data, and compliance demonstration procedures).

At the conclusion of these presentations, the public hearing on the proposed revisions to the *Guideline* was convened. The public hearing was held on the second half of the first day and on the second day of the conference. There were 26 presentations by stakeholders and interested parties. The EPA presentations and the presentations from the public hearing are provided in

the docket for this action. A transcript of the conference proceedings is also available in the docket. Additionally, all of the material associated with the Eleventh Modeling Conference and the public hearing are available on the EPA's SCRAM Web site at <https://www3.epa.gov/ttn/scram/11thmodconf.htm>.

### IV. Discussion of Public Comments on the Proposed Changes to the Guideline

In this action, the EPA is finalizing two types of revisions to the *Guideline*. The first type involves substantive changes to address various topics, including those presented and discussed at the Tenth and Eleventh Modeling Conferences. These revisions to the *Guideline* include enhancements to the formulation and application of the EPA's preferred dispersion modeling system, AERMOD, and the incorporation of a tiered demonstration approach to address the secondary chemical formation of ozone and PM<sub>2.5</sub> associated with precursor emissions from single sources. The second type of revision involves editorial changes to update and reorganize information throughout the *Guideline*. These latter revisions are not intended to meaningfully change the substance of the *Guideline*, but rather to make the *Guideline* easier to use and to streamline the compliance assessment process.

The EPA recognizes that the scope and extent of the final changes to the *Guideline* may not address all of the current concerns identified by the stakeholder community or emerging science issues. The EPA is committed to ensuring in the future that the *Guideline* and associated modeling guidance reflect the most up-to-date science and will provide appropriate and timely updates. Adhering to the existing procedures under CAA section 320, which requires the EPA to conduct a conference on air quality modeling at least every 3 years, the Twelfth Conference on Air Quality Modeling will occur within the next 2 years to provide a public forum for the EPA and the stakeholder community to engage on technical issues, introduce new air quality modeling research and techniques, and discuss recommendations on future areas of air quality model development and subsequent revisions to the *Guideline*. A formal notice announcing the next Conference on Air Quality Modeling will be published in the **Federal Register** at the appropriate time and will provide information to the stakeholder community on how to register to attend and/or present at the conference.

<sup>1</sup> See Docket ID No. EPA-HQ-OAR-2015-0310.

### A. Final Action

In this section, we offer summaries of the substantive comments received and our responses and explain the final changes to the *Guideline* in terms of the main technical and policy concerns addressed by the EPA. A more comprehensive discussion of the public comments received and our responses is provided in the Response to Comments document located in the docket for this action.

Air quality modeling involves estimating ambient concentrations using scientific methodologies selected from a range of possible methods, and should utilize the most advanced practical technology that is available at a reasonable cost to users, keeping in mind the intended uses of the modeling and ensuring transparency to the public. With these revisions, we believe that the *Guideline* continues to reflect scientific advances in the field and balances these important considerations for regulatory assessments. This action amends appendix W of 40 CFR part 51 as detailed below:

#### 1. Clarifications To Distinguish Requirements From Recommendations

We proposed revisions to the *Guideline* to provide clarity in distinguishing requirements from recommendations while noting the continued flexibilities provided within the *Guideline*, including but not limited to use and approval of alternative models. The vast majority of the public comments were supportive of the overall proposed reorganization and revisions to the regulatory text. There were only a few comments specific to the distinction between requirements and recommendations. All but one of these comments commended the EPA for providing this level of clarity of what is required in regulatory modeling demonstrations and where there is appropriate flexibility in the technique or approach. One comment expressed a concern that allowing for flexibility is critical when regulations, standards, and modeling techniques are constantly evolving. In this final action, the EPA reaffirms that significant flexibility and adaptability remain in the *Guideline*, while the revisions we are adopting serve to provide clarity in portions of the *Guideline* that have caused confusion in the past.

As discussed in the preamble to the proposed rule, the EPA's PSD permitting regulations specify that "[a]ll applications of air quality modeling involved in this subpart shall be based on the applicable models, data bases, and other requirements specified in

appendix W of this part (*Guideline on Air Quality Models*)." 40 CFR 51.166(l)(1); see also 40 CFR 52.21(l)(1). The "applicable models" are the preferred models listed in appendix A to appendix W to 40 CFR part 51. However, there was some ambiguity in the past with respect to the "other requirements" specified in the *Guideline* that must be used in PSD permitting analysis and other regulatory modeling assessments.

Ambiguity could arise because the *Guideline* generally contains "recommendations" and these recommendations are expressed in non-mandatory language. For instance, the *Guideline* frequently uses "should" and "may" rather than "shall" and "must." This approach is generally preferred throughout the *Guideline* because of the need to exercise expert judgment in air quality analysis and the reasons discussed in the *Guideline* that "dictate against a strict modeling 'cookbook'." 40 CFR part 51, appendix W, section 1.0(c).

Considering the non-mandatory language used throughout the *Guideline*, the EPA's Environmental Appeals Board observed:

Although appendix W has been promulgated as codified regulatory text, appendix W provides permit issuers broad latitude and considerable flexibility in application of air quality modeling. Appendix W is replete with references to "recommendations," "guidelines," and reviewing authority discretion.

*In Re Prairie State Generating Company*, 13 E.A.D. 1, 99 (EAB 2005) (internal citations omitted).

Although this approach appears throughout the *Guideline*, there are instances where the EPA does not believe permit issuers should have broad latitude. Some principles of air quality modeling described in the *Guideline* must always be applied to produce an acceptable analysis. Thus, to promote clarity in the use and interpretation of the revised *Guideline*, we are finalizing the specific use of mandatory language, as proposed, along with references to "requirements," where appropriate, to distinguish requirements from recommendations in the application of models for regulatory purposes.

#### 2. Updates to EPA's AERMOD Modeling System

In our proposed action, we invited comments on the proposed scientific updates to the regulatory version of the AERMOD modeling system, including:

1. A proposed "ADJ\_U\*" option incorporated in AERMET to adjust the surface friction velocity ( $u^*$ ) to address issues with AERMOD model tendency

to overprediction from some sources under stable, low wind speed conditions.

2. A proposed "LOWWIND3" option in AERMOD to address issues with model tendency to overprediction under low wind speed conditions. The low wind option increases the minimum value of the lateral turbulence intensity ( $\sigma_v$ ) from 0.2 to 0.3 and adjusts the dispersion coefficient to account for the effects of horizontal plume meander on the plume centerline concentration. It also eliminates upwind dispersion, which is incongruous with a straight-line, steady-state plume dispersion model, such as AERMOD.

3. Modifications to AERMOD formulation to address issues with model tendency to overprediction for applications involving relatively tall stacks located near relatively small urban areas.

4. Proposed regulatory options in AERMOD to address plume rise for horizontal and capped stacks based on the July 9, 1993, Model Clearinghouse memorandum,<sup>2</sup> with adjustments to account for the Plume Rise Model Enhancements (PRIME) algorithm for sources subject to building downwash.

5. A proposed buoyant line source option, based on the Buoyant Line and Point Source (BLP) model, incorporated in AERMOD.

6. Proposed updates to the NO<sub>2</sub> Tier 2 and Tier 3 screening techniques coded within AERMOD.

The EPA's final action related to each of these proposed updates is discussed below.

#### Incorporation of the ADJ\_U\* Option Into AERMET

The EPA has integrated the ADJ\_U\* option into the AERMET meteorological processor for AERMOD to address issues with model overprediction of ambient concentrations from some sources associated with underprediction of the surface friction velocity ( $u^*$ ) during light wind, stable conditions. The proposed update to AERMET included separate ADJ\_U\* algorithms for applications with and without the Bulk Richardson Number (BULKRN) option in AERMET. The ADJ\_U\* option with BULKRN utilizes measured vertical temperature difference data (*i.e.*, delta-T data) and is based on Luhar and Rayner (2009, BLM v.132). The ADJ\_U\*

<sup>2</sup> U.S. Environmental Protection Agency, 1993. Proposal for Calculating Plume Rise for Stacks with Horizontal Releases or Rain Caps for Cookson Pigment, Newark, New Jersey. Memorandum dated July 9, 1993, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scrain/guidance/mch/new\\_mch/R1076\\_TIKVART\\_9\\_JUL\\_93.pdf](https://www3.epa.gov/ttn/scrain/guidance/mch/new_mch/R1076_TIKVART_9_JUL_93.pdf).

option without BULKRN does not utilize delta-T data and is based on Qian and Venkatram (2011, BLM v. 138). These studies also include meteorological evaluations of predicted versus observed values of  $u^*$ , which demonstrate improved skill in predicting  $u^*$  during stable light wind conditions, and we consider these meteorological evaluations as key components of the overall technical assessment of these model formulation changes.

The majority of public comments supported the adoption of the ADJ\_U\* option in AERMET, while a few commenters expressed concern regarding the potential for the ADJ\_U\* option to underestimate ambient concentrations. Some commenters also expressed concern regarding the appropriateness of the field study databases used in the EPA model evaluations. We acknowledge the issues and potential challenges associated with conducting field studies for use in model performance evaluations, especially during stable light wind conditions, given the potentially high degree of variability that may exist across the modeling domain and the increased potential for microscale influences on plume transport and dilution. This variability is one of the reasons that we discourage placing too much weight on modeled versus predicted concentrations paired in time and space in model performance evaluations. This also highlights the advantages of conducting field studies that utilize circular arcs of monitors at several distances to minimize the potential influence of uncertainties associated with the plume transport direction on model-to-monitor comparisons. The 1974 Idaho Falls, Idaho, and 1974 Oak Ridge, Tennessee, field studies,<sup>3,4</sup> conducted by the National Oceanic and Atmospheric Administration (NOAA), are two of the key databases included in the evaluation of the ADJ\_U\* option in AERMET (as well as the LOWWIND3 option in AERMOD), and both utilized circular arcs of monitors at 100 meter (m), 200 m, and 400 m downwind of the tracer release point.

Initial evaluations of the ADJ\_U\* option in AERMET and LOWWIND options in AERMOD were first

presented as “beta” options in appendix F of the AERMOD User’s Guide Addendum for version 12345. This included results for the Idaho Falls and Oak Ridge field studies. Updated evaluations based on these NOAA studies were included in the AERMOD User’s Guide Addendum for v15181, along with additional evaluations for the Lovett database involving a tall stack with nearby complex terrain. Additional evaluations of these proposed modifications to AERMET and AERMOD were also presented at the Eleventh Modeling Conference, including an evaluation based on the 1993 Cordero Mine PM<sub>10</sub> field study in Wyoming, as summarized in the Response to Comments document.

One commenter provided a detailed modeling assessment of the proposed ADJ\_U\* option in AERMET (as well as the proposed LOWWIND3 option in AERMOD) across a number of field studies to support their position that the proposed model updates will “reduce model accuracy” and “in some cases quite significantly reduce[s] modeled impacts, particularly so in the case of the Tracy validation study data.” The EPA’s review of the modeling results provided by the commenter indicated almost no influence of the ADJ\_U\* option on those field studies associated with tall stacks in flat terrain, including the Baldwin and Kincaid field studies. These results are expected since the “worst-case” meteorological conditions for tall stacks in flat terrain generally occur during daytime convective conditions that are not affected by the ADJ\_U\* option. In addition, the commenter’s modeling results presented for the Lovett field study, a tall stack with nearby complex terrain, appear to show improved performance (with less underprediction) with the ADJ\_U\* option as compared to the default option in AERMET, thereby supporting use of the ADJ\_U\* option in appropriate situations.

The commenter also stated that the issue of underprediction with the ADJ\_U\* option is “particularly so in the case of the Tracy validation study.” The Tracy field study involved a tall stack located with nearby terrain similar to the Lovett field study; however, the Tracy field study differs from the Lovett and other complex terrain field studies in that Tracy had the most extensive set of site-specific meteorological data, including several levels of wind speed, wind direction, ambient temperature, and turbulence parameters (*i.e.*, sigma-theta and/or sigma-w), extending from 10 m above ground up to 400 m above ground for some parameters. The Tracy field study also included the largest

number of ambient monitors of any complex terrain study used in evaluating AERMOD performance, including 106 monitors extending across a domain of about 75 square kilometers, and used sulfur hexafluoride (SF<sub>6</sub>) as a tracer which reduces uncertainty in evaluating model performance by minimizing the influence of background concentrations on the model-to-monitor comparisons. The EPA’s review of the commenter’s results for the Tracy database confirms their finding of a bias toward underprediction by almost a factor of two with the ADJ\_U\* option in AERMET, compared to relatively unbiased results with the default option in AERMET based on the full set of meteorological inputs. However, there was no diagnostic performance evaluation included with the commenter’s analysis that could provide the necessary clarity regarding the potential connection between the ADJ\_U\* option and cause for the bias to underpredict concentrations.

After proposal, the EPA received several requests through its Model Clearinghouse (MCH) for alternative model approval of the ADJ\_U\* option under section 3.2.2 of the *Guideline*. The EPA issued two MCH concurrences on February 10, 2016, for the Donlin Gold, LLC mining facility in EPA Region 10 (*i.e.*, ground level, fugitive emissions of particulate matter from sources with low release heights during periods of low-wind/stable conditions), and on April 29, 2016, for the Schiller Station facility in EPA Region 1 (*i.e.*, SO<sub>2</sub> emissions from tall stack sources with impacts on distant complex terrain, during low-wind/stable conditions). In both cases, the request memoranda from the EPA Regions to the MCH noted the potential for underprediction by AERMOD with the ADJ\_U\* option in situations where turbulence data from site-specific meteorological data inputs were also used. Through the MCH concurrence for each case, the EPA acknowledged the potential for this underprediction and effectively communicated to the stakeholder community that these turbulence data were not used in the approved alternative model. There was no detailed diagnostic performance evaluation included with the MCH requests to provide insights regarding the potential connection between the ADJ\_U\* option and use of on-site turbulence data.

To evaluate the public comments in light of these MCH concurrences, the EPA has conducted additional meteorological data degradation analyses for the Tracy field study and

<sup>3</sup>NOAA Technical Memorandum ERL ARL-52, 1974. Diffusion under Low Wind Speed, Inversion Conditions. Sagendorf, J.F., C. Dickson. Air Resources Laboratory, Idaho Falls, Idaho.

<sup>4</sup>NOAA Technical Memorandum ERL ARL-61, 1976. Diffusion under Low Wind Speed Conditions near Oak Ridge, Tennessee. Wilson, R.B., G. Start, C. Dickson, N. Ricks. Air Resources Laboratory, Idaho Falls, Idaho.

the 1972 Idaho Falls field study for a ground-level release in flat terrain to provide a better understanding of the nature of the tendency to underpredict concentrations when applying the ADJ\_U\* option with site-specific turbulence measurements. The full meteorological dataset available for the Tracy field study provides a robust case study for this assessment because it includes several levels of turbulence data, *i.e.*, sigma-theta (the standard deviation of horizontal wind direction fluctuations) and/or sigma-w (the standard deviation of the vertical wind speed fluctuations), in addition to several levels of wind speed, direction and temperature. The 1972 Idaho Falls field study also included a robust set of meteorological data to assess this potential issue for ground-level sources.

The results of this EPA study confirm good performance for the Tracy field study using the full set of meteorological inputs with the default options (*i.e.*, without the ADJ\_U\* option in AERMET and without any LOWWIND option in AERMOD). Including the ADJ\_U\* option in AERMET with full meteorological data results in an underprediction of about 40 percent. On the other hand, AERMOD results without the ADJ\_U\* option in AERMET and without the observed profiles of temperature and turbulence (*i.e.*, mimicking standard airport meteorological inputs) results in significant overprediction by about a factor of 4. However, using the ADJ\_U\* option with the degraded meteorological data shows very good agreement with observations, comparable to or slightly better than the results with full meteorological inputs. Full results from this study to assess the use of the ADJ\_U\* option with various levels of meteorological data inputs are detailed in our Response to Comments document provided in the docket for this action. The Response to Comments document also provides evidence of this potential bias toward underprediction when the ADJ\_U\* option is applied for applications that also include site-specific meteorological data with turbulence parameters based on the 1972 Idaho Falls study. As with the Tracy field study, the Idaho Falls field study results with site-specific turbulence data do not show a bias toward underprediction without the ADJ\_U\* option, but do show a bias toward underprediction using turbulence data with the ADJ\_U\* option.

Based on these detailed findings, the public cannot be assured that the proposed ADJ\_U\* option, when used with site-specific meteorological inputs

including turbulence data (*i.e.*, sigma-theta and/or sigma-w), would not bias model predictions towards underestimation, which would be inconsistent with section 3.2.2 of the *Guideline*. Therefore, the EPA has determined that the ADJ\_U\* option should not be used in AERMET in combination with use of measured turbulence data because of the observed tendency for model underpredictions resulting from the combined influences of the ADJ\_U\* and the turbulence parameters within the current model formulation.

While these findings suggest that the ADJ\_U\* option is not appropriate for use in regulatory applications involving site-specific meteorological data that include measured turbulence parameters, the model performance and diagnostic evaluations strongly support the finding that the ADJ\_U\* option provides for an appropriate adjustment to the surface friction velocity parameter when standard National Weather Service (NWS) airport meteorological data, site-specific meteorological data without turbulence parameters, or prognostic meteorological input data are used for the regulatory application.

Therefore, based on these findings of improved model performance with the ADJ\_U\* option for sources where peak impacts are likely to occur during low wind speed and stable conditions, as well as the peer-reviewed studies demonstrating improved estimates of the surface friction velocity ( $u^*$ ) based on these options, the EPA is adopting the proposed ADJ\_U\* option in AERMET as a regulatory option for use in AERMET for sources using standard NWS airport meteorological data, site-specific meteorological data without turbulence parameters, or prognostic meteorological inputs derived from prognostic meteorological models.

#### Incorporation of the LOWWIND3 Option Into AERMOD

In addition to the ADJ\_U\* option in AERMET, the EPA also proposed the incorporation of LOWWIND3 as a regulatory option in AERMOD to address issues with model overprediction for some sources under low wind speed conditions. Beginning with version 12345 of AERMOD, two LOWWIND “beta” options were included in AERMOD (*i.e.*, LOWWIND1 and LOWWIND2), and a third option, LOWWIND3, was incorporated at the time of proposal in version 15181 of AERMOD. The LOWWIND options modify the minimum value of sigma-v, the lateral turbulence intensity, which is used to determine the lateral plume dispersion coefficient (*i.e.*, sigma-y).

With respect to the specific issue of setting a minimum value of sigma-v, the LOWWIND options can be considered as empirical options based on applicable parameter specifications from the scientific literature. However, the LOWWIND options go beyond this empirical specification of the minimum sigma-v parameter to address the horizontal meander component in AERMOD that also contributes to lateral plume spread, especially during low wind, stable conditions. Furthermore, since the horizontal meander component in AERMOD is a function of the “effective” sigma-v value, lateral plume dispersion may be further enhanced under the LOWWIND3 option by increased meander, beyond the influence of the minimum sigma-v value alone.

The current default option in AERMOD uses a minimum sigma-v of 0.2 meters per second (m/s). Setting a higher minimum value of sigma-v would tend to increase lateral dispersion during low wind conditions and, therefore, could reduce predicted ambient concentrations. It is also worth noting that the values of sigma-v derived in AERMOD are based on the dispersion parameters generated in AERMET (*i.e.*, the surface friction velocity ( $u^*$ ) and the convective velocity scale ( $w^*$ )), as well as the user-specified surface characteristics (*i.e.*, the surface roughness length, Bowen ratio, and albedo) used in processing the meteorological inputs through AERMET. As a result, application of the ADJ\_U\* option in AERMET will tend to increase sigma-v values in AERMOD and generally tend to lower predicted peak concentrations, separate from application of the LOWWIND options. Unlike the proposed ADJ\_U\* option in AERMET that adjusts  $u^*$  under stable conditions, the LOWWIND options in AERMOD are applied for both stable and unstable/convective conditions. However, since atmospheric turbulence will generally be higher during unstable/convective conditions than for stable conditions, the potential influence of the minimum sigma-v value on plume dispersion is likely to be much less important during unstable/convective conditions.

The majority of commenters supported the EPA’s proposal to incorporate the LOWWIND3 option into the regulatory version of AERMOD because they believed it would provide a more realistic treatment of low wind situations and reduce the potential for overprediction of the current regulatory version of AERMOD for such conditions. However, one commenter indicated that the proposed

LOWWIND3 option in AERMOD will “reduce model accuracy” along with model results, showing a tendency for underprediction across a number of evaluation databases. As discussed in the Response to Comments document, the influence of the LOWWIND3 option on model performance is mixed, and has shown a tendency toward underprediction with increasing distance in some cases, especially when LOWWIND3 is applied in conjunction with the ADJ\_U\* option in AERMET. The EPA’s reassessment of model performance confirmed this finding of underprediction with increasing distance, in particular for the 1972 Idaho Falls field study database (discussed previously) and the Prairie Grass, Kansas, field study, which involved a near-surface tracer release in flat terrain. As noted above, there is an interaction between the ADJ\_U\* option and LOWWIND options because the values of sigma-v derived in AERMOD are based on the surface friction velocity (u\*) parameter generated in AERMET. As a result, the ADJ\_U\* option in conjunction with the LOWWIND3 option influences the AERMOD derived sigma-v parameter and, in some cases, may exacerbate the tendency for AERMOD with LOWWIND3 to underpredict at higher concentrations, as shown in the commenter’s assessment and the EPA’s reassessment.

Another aspect of the AERMOD model formulation that may contribute to an increasing bias toward underprediction with distance is the treatment of the “inhomogeneous boundary layer” (IBL) that accounts for changes in key parameters such as wind speed and temperature with height above ground. The IBL approach determines “effective” values of wind speed, temperature, and turbulence that are averaged across a layer of the plume between the plume centerline height and the height of the receptor. The extent of this layer depends on the vertical dispersion coefficient (*i.e.*, sigma-z). Therefore, as the plume grows downwind of the source, the extent of the layer used to calculate the effective parameters will increase (up to specified limits). The potential influence of this aspect of AERMOD formulation on modeled concentrations will depend on several factors, including source characteristic, meteorological condition, and the topographic characteristics of the modeling domain.

Several commenters recommended that the EPA’s proposed revisions to AERMOD be further evaluated given either the lack or paucity of peer-reviewed literature upon which they are based. Specifically, one commenter

noted that “while this overprediction phenomenon can occur under certain conditions, additional studies produced by a more diverse group of organizations should be evaluated.” Unlike the situation with the ADJ\_U\* option, the EPA does not have a published, peer-reviewed model formulation update with supporting model performance evaluations that fully address the complex issues of concern for the LOWWIND options. Therefore, the EPA agrees with commenters that additional study and evaluation is warranted for the proposed LOWWIND3 option, as well as other low wind options, in order to gain the understanding across the modeling community that is necessary to determine whether it would be appropriate to incorporate it into an EPA-preferred model used to inform regulatory decisions. The EPA will continue to work with the modeling community to further assess the theoretical considerations and model performance results under relevant conditions to inform considerations for appropriate adjustments to the default minimum value of sigma-v from 0.2 m/s that, as noted by some commenters, may be considered separate from any specific LOWWIND option.

Based on EPA’s review of public comments and further consideration of the issues, the public cannot be assured that the proposed LOWWIND3 option does not have a tendency to bias model predictions towards underestimation (especially in combination with the ADJ\_U\* option and/or site-specific turbulence parameters), which would be inconsistent with section 3.2.2 of the *Guideline*. Therefore, lacking sufficient evidence to support adoption of LOWWIND3 (or other LOWWIND options) as a regulatory option in AERMOD, we are not incorporating LOWWIND3 as a regulatory option in AERMOD at this time, and we are deferring action on the LOWWIND options in general pending further analysis and evaluation in conjunction with the modeling community.

#### Modifications to AERMOD Formulation for Tall Stack Applications Near Small Urban Areas

As proposed, the EPA recognized the need to address observed overpredictions by AERMOD when applied to situations involving tall stacks located near small urban areas. The tendency to overpredict concentrations results from an unrealistic limit on plume rise imposed within the dispersion model. The EPA received broad support in the public comments for these proposed modifications to the AERMOD

formulation that appropriately address overprediction for applications involving relatively tall stacks located near small urban areas. The EPA is finalizing this model formulation update, as proposed, into the regulatory version of AERMOD.

#### Address Plume Rise for Horizontal and Capped Stacks in AERMOD

As proposed, the EPA updated the regulatory options in AERMOD to address plume rise for horizontal and capped stacks based on the July 9, 1993, MCH memorandum,<sup>2</sup> with adjustments to account for the PRIME algorithm for sources subject to building downwash. There was broad-based support for this model update across the public comments. One commenter noted that the use of this proposed option for horizontal stacks, although a better method than the previous version, can lead to extremely high concentrations for sources with building downwash in complex terrain. Despite the noted improved performance of the proposed option in the case of building downwash, the EPA recognizes the ongoing issues with this option in the presence of building downwash and with its inherent complexities and its particular application in such situations with complex terrain. The EPA also recognizes that the appropriateness of this option for that particular situation would be a matter of consultation with the appropriate reviewing authority. However, given the broad support stated in public comments for the improved treatment, the EPA is finalizing this formulation update, as proposed, as a regulatory option within AERMOD.

#### Incorporation of the BLP Model Into AERMOD

As proposed, the EPA has integrated the BLP model into the AERMOD modeling system and removed BLP from appendix A as a preferred model. The comments received on the BLP integration into AERMOD are summarized in four categories: (1) Strongly supportive of the integration and replacement of BLP; (2) supportive of the integration, but with concerns that the integration of BLP is not fully consistent with the dispersion algorithms in AERMOD; (3) supportive of the integration, but suggestive that more time is needed to evaluate the implementation and that BLP should remain in appendix A until more evaluation can be made of the new code; and (4) concerned that modeled concentrations between the original BLP and BLP integrated in AERMOD are not identical. Despite the concerns expressed, all the comments received

were supportive of the concept of integrating the two models and removing BLP from appendix A.

The EPA's integration of BLP into AERMOD was not intended to update the model science within BLP into AERMOD. Thus, while the comments relating to inconsistencies between AERMOD (e.g., based on Monin-Obukhov length and similarity profiling) and BLP (e.g., based on Pasquill-Gifford stability classes) are largely accurate, they do not affect the status of the proposed BLP integration. Many of the comments on the proposal suggested that the EPA needs to more quickly integrate updates to the AERMOD modeling system to address these inconsistencies. However, the EPA does not find it appropriate to delay the release of the integrated model, particularly since the stated purpose of the integration and evaluation is to assure equivalency and not a fundamental update to the BLP model science to be consistent with that of AERMOD, which would require additional time and effort to appropriately inform a possible future EPA action. The EPA appreciates the comments identifying potential issues where model equivalency was not fully demonstrated. These instances have been further evaluated and corrections have been made to the code to sufficiently address these issues. The details of these corrections, along with the comments relating to inconsistencies in underlying dispersion science, are addressed in detail in the Response to Comments document located in the docket for this action.

Therefore, the EPA is integrating the BLP model into the AERMOD modeling system, is removing BLP from appendix A as an EPA-preferred model, and is updating the summary description of the AERMOD modeling system to appendix A of the *Guideline* as proposed.

#### Updates to the NO<sub>2</sub> Tier 2 and Tier 3 Screening Techniques in AERMOD

In the proposed action, we solicited comments on whether we have reasonably addressed technical concerns regarding the 3-tiered demonstration approach and specific NO<sub>2</sub> screening techniques within AERMOD and whether we were on sound foundation to recommend the proposed updates. Section 5.2.4 of the 2005 version of the *Guideline* details a 3-tiered approach for assessing nitrogen oxides (NO<sub>x</sub>) sources, which was recommended to obtain annual average estimates of NO<sub>2</sub> concentrations from point sources for purposes of NSR

analyses and for SIP planning purposes. This 3-tiered approach addresses the co-emissions of nitric oxide (NO) and NO<sub>2</sub> and the subsequent conversion of NO to NO<sub>2</sub> in the atmosphere. In January 2010, the EPA promulgated a new 1-hour NO<sub>2</sub> NAAQS (75 FR 6474). Prior to the adoption of the 1-hour NO<sub>2</sub> standard, few PSD permit applications required the use of Tier 3 options, and guidance available at the time did not fully address the modeling needs for a 1-hour standard (i.e., tiered approaches for NO<sub>2</sub> in the 2005 version of the *Guideline* specifically targeted an annual standard). In response to the 1-hour NO<sub>2</sub> standard, the EPA proposed the incorporation of several modifications to the Tier 2 and Tier 3 NO<sub>2</sub> screening techniques as regulatory options in AERMOD, so that alternative model approval would no longer be needed.

The proposed modifications specifically included: (1) Replacing the existing Tier 2 Ambient Ratio Method (ARM)<sup>5</sup> with a revised Ambient Ratio Method 2 (ARM2)<sup>6</sup> approach; and (2) incorporating the existing detailed screening option of the Ozone Limiting Method (OLM)<sup>7</sup> and updated version of the Plume Volume Molar Ratio Method (PVMRM)<sup>8</sup> as regulatory options in AERMOD as preferred Tier 3 screening methods for NO<sub>2</sub> modeling. The vast majority of the public comments supported the proposed changes to these methods. However, there were two subsets of comments that required additional response.

First, several commenters stated that the proposed default NO<sub>2</sub>/NO<sub>x</sub> minimum ambient ratio (MAR) of 0.5, for use with the ARM2 approach, was too high and that a MAR of 0.2 should be used instead. The MAR is the lowest NO<sub>2</sub>/NO<sub>x</sub> ratio used in the ARM2 method at the highest NO<sub>x</sub> levels. The MAR increases from this minimum level to a maximum NO<sub>2</sub>/NO<sub>x</sub> ratio of 0.9 at the lowest NO<sub>x</sub> levels. While commenters believe that the MAR of 0.2 is more representative of ambient data, the EPA maintains that consistency in

<sup>5</sup> Chu, S.H. and E.L. Meyer, 1991. Use of Ambient Ratios to Estimate Impact of NO<sub>x</sub> Sources on Annual NO<sub>2</sub> Concentrations. Proceedings, 84th Annual Meeting & Exhibition of the Air & Waste Management Association, June 16–21 1991, Vancouver, B.C.

<sup>6</sup> Podrez, M. 2015. An Update to the Ambient Ratio Method for 1-h NO<sub>2</sub> Air Quality Standards Dispersion Modeling. *Atmospheric Environment*, 103: 163–170.

<sup>7</sup> Cole, H.S. and J.E. Summerhays, 1979. A Review of Techniques Available for Estimation of Short-Term NO<sub>2</sub> Concentrations. *Journal of the Air Pollution Control Association*, 29(8): 812–817.

<sup>8</sup> Hanrahan, P.L., 1999. The Polar Volume Polar Ratio Method for Determining NO<sub>2</sub>/NO<sub>x</sub> Ratios in Modeling—Part I: Methodology. *Journal of the Air & Waste Management Association*, 49: 1324–1331.

the tiered approach for NO<sub>2</sub> modeling, with the Tier 2 methods being more conservative than the Tier 3 methods, is needed and that national default model inputs need to be conservative, in line with the CAA's objective to prevent potential NAAQS violations. The revised text allows for alternative MARs that should not be overly difficult to justify to the appropriate reviewing authority when lower MARs are appropriate. The EPA reaffirms that site-specific data are always preferred, but provides the national default model inputs when these data are unavailable.

Second, several commenters noted that the specific version of PVMRM2 intended for regulatory use was not entirely clear. Version 15181 of AERMOD included both PVMRM and PVMRM2 with the proposal preamble text indicating that we would be promulgating PVMRM2; however, the proposed regulatory text identified PVMRM, which caused confusion. The methodology employed in the "PVMRM2" option in AERMOD version 15181 is now the "PVMRM" regulatory option in AERMOD, and the methodology employed in the "PVMRM" option in AERMOD version 15181 has been removed entirely from the model. The basis for this decision is that the updated PVMRM2 is a more complete implementation of the PVMRM approach outlined by Hanrahan (1999) than the original PVMRM implementation in AERMOD.

Therefore, the EPA is updating the regulatory version of the AERMOD modeling system to reflect these changes for NO<sub>2</sub> modeling and has updated the related descriptions of the AERMOD modeling system in section 4.2.3.4 of the *Guideline* as proposed.

#### EPA's Preferred Version of the AERMOD Modeling System

As described throughout section IV.A.2 of this preamble, we are revising the summary description of the AERMOD modeling system in appendix A of the *Guideline* to reflect these updates. Model performance evaluation and scientific peer review references for the updated AERMOD modeling system are cited, as appropriate. An updated user's guide and model formulation documents for version 16216 are located in the docket for this action. The essential codes, preprocessors, and test cases have been updated and posted on the EPA's SCRAM Web site at <https://www.epa.gov/scram/air-quality-dispersion-modeling-preferred-and-recommended-models#aermod>.

### 3. Status of AERSCREEN

In our proposed action, we invited comment on the incorporation of AERSCREEN into the *Guideline* as the recommended screening model for AERMOD that may be suitable for applications in all types of terrain and for applications involving building downwash. AERSCREEN uses the EPA's preferred near-field dispersion model AERMOD in screening mode and represents the state of the science versus the outdated algorithms of SCREEN3 that are based on the Industrial Source Complex model (ISC).

We received some comments that SCREEN3 should be retained as it is simpler to use than AERSCREEN. The EPA disagrees with those comments and reminds users that AERSCREEN is already being utilized by much of the stakeholder community and represents the state of the science as stated in the paragraph above. Given the preferred status of AERMOD over ISC and the fact that AERSCREEN is now incorporating fumigation, an option available in SCREEN3, we feel that there are no valid technical reasons to retain SCREEN3 as a recommended screening model.

We also received comments expressing concerns about the fumigation options and conservatism of the fumigation outputs. The fumigation options implemented in AERSCREEN are the same algorithms used in SCREEN3, such that the current capabilities in that screening model are now available in AERSCREEN. However, these fumigation options take advantage of the AERMOD equations for the dispersion parameters sigma-y and sigma-z that are needed for the fumigation calculations. AERSCREEN also takes advantage of the meteorological data generated by MAKEMET to calculate those parameters based on the boundary layer algorithms included in AERMET, as opposed to using standard dispersion curves used by SCREEN3. Some commenters suggested that the Shoreline Dispersion Model (SDM) algorithms be investigated for fumigation calculations. We agree with these commenters and will investigate the incorporation of the SDM algorithms in AERSCREEN for a future release. One commenter noted a bug in building outputs when running AERSCREEN with downwash and user-supplied BPIPPRM input files. The commenter stated that AERSCREEN takes the maximum and minimum dimensions over the 36 directions output by BPIPPRM for use in modeling. For some directions, there may be no building

influence and AERSCREEN erroneously takes a zero dimension as a building width. The EPA has determined that this is not a bug in AERSCREEN. Rather, it is a product of the output of BPIPPRM, which may report a value of zero for building widths and, thus, AERSCREEN reports a value of zero as a minimum building width. To address this issue, we have modified AERSCREEN to only output non-zero widths.

Finally, several commenters pointed out a typographical error in the AERSCREEN conversion factors from 1-hour to 3-, 8-, and 24-hour and annual results in section 4.2.1.1 of the *Guideline*. The original text reported the SCREEN3 factors and not the AERSCREEN factors listed in the AERSCREEN user's guide. These factors have been corrected in the final revisions to the *Guideline* to reflect the AERSCREEN factors. Another commenter also found a typographical error in section 4.2.1.1(c) where BPIPPRM was misspelled. This too was corrected. We also received a comment that the term "unresolvable" in section 4.2.1.3(c) implies that a problem cannot be solved. Suggested language of "unforeseen challenges" was suggested. We agreed that the "unresolvable" is erroneous and changed the term to "unforeseen."

Therefore, the EPA is incorporating AERSCREEN into the *Guideline* as the recommended screening model for AERMOD that may be used in applications across all types of terrain and for applications involving building downwash.

### 4. Status of CALINE3 Models

We solicited comment on our proposal to replace CALINE3<sup>9</sup> with AERMOD as the preferred appendix A model for its intended regulatory applications, primarily determining near-field impacts for primary emissions from mobile sources for PM<sub>2.5</sub>, PM<sub>10</sub>, and carbon monoxide (CO) hot-spot analyses.<sup>10</sup> This proposed action was based on the importance of reflecting the latest science in AERMOD, its improved model performance over CALINE3, and the availability of more representative meteorological data for

<sup>9</sup> Benson, Paul E., 1979. CALINE3—A Versatile Dispersion Model for Predicting Air Pollutant Levels Near Highways and Arterial Streets. Interim Report, Report Number FHWA/CA/TL-79/23. Federal Highway Administration, Washington, DC (NTIS No. PB 80-220841).

<sup>10</sup> U.S. Environmental Protection Agency, 2015. Transportation Conformity Guidance for Quantitative Hot-Spot Analyses in PM<sub>2.5</sub> and PM<sub>10</sub> Nonattainment and Maintenance Areas. Publication No. EPA-420-B-15-084. Office of Transportation and Air Quality, Ann Arbor, MI.

use in AERMOD. The EPA's proposal also set forth a 1-year transition period for the adoption of AERMOD for all regulatory applications.

The mobile source modeling applications under the CAA requirements that are most affected by the replacement of CALINE3 with AERMOD are transportation conformity hot-spot analyses for PM<sub>2.5</sub>, PM<sub>10</sub>, and CO.<sup>11</sup> To date, PM hot-spot analyses have involved a refined analysis that can be accomplished with either AERMOD or CAL3QHCR (a variant of CALINE3).<sup>12</sup> For CO hot-spot analyses, screening analyses are typically conducted with CAL3QHC (a variant of CALINE3).<sup>12</sup>

The EPA received several comments supporting and several comments opposed to the proposed replacement of CALINE3 with AERMOD as the preferred appendix A model for mobile source emissions. The commenters who supported the proposed replacement agreed with the reasons set forth in the proposal, mainly that AERMOD reflects the state-of-the-science for Gaussian plume dispersion models, with on-going updates and enhancements supported by the EPA, has more accurate performance and is more flexible and can be applied to more project types than other dispersion models, can utilize more recent and more representative meteorological data, and that a single model will generally streamline the process of conducting and securing approval of model demonstrations.<sup>13</sup> Alternatively, the commenters who did not support the proposal believed: that the science indicating AERMOD has more accurate performance is unclear; that AERMOD would increase the time required to complete hot-spot analyses, particularly for CO screening; and that a longer transition period, such as a 3-year period, would be needed for the adoption of new models for conformity analyses.

The adverse comments related to the sufficiency of the EPA's technical and scientific basis for the replacement of

<sup>11</sup> Transportation conformity is required under Clean Air Act section 176(c) for federally funded or approved transportation projects in nonattainment and maintenance areas; EPA's transportation conformity regulations can be found at 40 CFR part 93.

<sup>12</sup> U.S. Environmental Protection Agency, 1992. Guideline for Modeling Carbon Monoxide from Roadway Intersections, EPA-454/R-92-005. Office of Air Quality Planning and Standards, RTP, NC.

<sup>13</sup> U.S. Environmental Protection Agency, 2016. Technical Support Document (TSD) for Replacement of CALINE3 with AERMOD for Transportation Related Air Quality Analyses. Publication No. EPA-454/B-16-006. Office of Air Quality Planning and Standards, Research Triangle Park, NC.



CALINE3 with AERMOD included statements that AERMOD does not have an explicit line-source algorithm; that the peer-reviewed literature shows mixed results for model assessments; and that AERMOD performance for roadways has not been as well documented for an array of transportation projects.

First, the EPA notes that, based on implementation of conformity requirements to date, the majority of PM hot-spot analyses have been conducted with AERMOD and its existing algorithms have been used to perform these analyses. While it is true that AERMOD does not have an explicit line-source algorithm, it does have a LINE source input pathway that mimics the input requirements for CALINE3 and simplifies using elongated area sources such as roadways. While roadway sources are often described as “line sources,” they are in fact three-dimensional entities. The roadway width is one of the model inputs for CALINE3 and the width of a roadway is frequently many times the distance from the edge of the roadway to the closest receptor. The actual formulation of these source types is not as explicit as the names suggest. For example, LINE source in AERMOD performs an explicit numerical integration of emissions from the LINE source, whereas CALINE uses a rough integration based on a series of finite line segments. Thus, an elongated area source in AERMOD is likely to represent the distribution of roadway emissions more accurately than the approach taken in CALINE3. In fact, the body of literature focused on roadway emissions suggests that the formulation of the Gaussian plume (*i.e.*, line, area or volume) is not as important as the appropriate settings of the source characteristics and the quality of the emissions and meteorological inputs (see discussion in the Response to Comments document in the docket for this action).

These commenters also believed that the Heist (2013) journal article<sup>14</sup> cited primarily as supporting the proposal was too limited in scope. The quality of the emissions inputs, in particular, is one of the reasons the EPA focused on Heist (2013) to support the proposal. The EPA reviewed current model assessments in the literature and found that the majority used traffic counts and an emissions model to estimate

emissions (see the Response to Comments document for more details). Although this approach introduces significant uncertainty in the model evaluation, this uncertainty was not addressed in these types of studies. Studies that use tracer emissions rather than traffic counts and emissions models remove this uncertainty and allow an evaluation of the dispersion model itself, rather than a joint evaluation of the emissions model and the dispersion model. The studies based on tracer releases rather than modeled emissions are limited to the CALTRANS99 and the 2008 Idaho Falls field studies examined in Heist (2013), and its robust model performance evaluations of these two studies. Thus, Heist (2013) was the primary literature the EPA considered in making a determination regarding AERMOD replacing CALINE3, rather than the small number of other recent model evaluations available in the peer-reviewed literature. Since the CALTRANS99 field campaign evaluated by Heist (2013) included an emission measurement system attached to vehicles driving on an operational highway, the results are fully representative of operational highways. The Heist (2013) study compared a developmental line-source model, RLINE, to AERMOD with volume and line sources as well as CALINE3 and CALINE4. RLINE showed nearly equivalent performance to the area and volume formulations from AERMOD. CALINE3 was clearly the worst performing model from the six model formulations evaluated. While CALINE4 had better performance than CALINE3, CALINE4 was still the second-worst performing model. It should also be noted that most recent literature only evaluates the CALINE4 model rather than the CALINE3 model, which further highlights that the CALINE3 model is outdated in its science, even within its own class of models.

In terms of regulatory applications, AERMOD has been demonstrated to be useful for a range of transportation applications and is generally relied on over CAL3QHCR for more complicated projects because of its greater flexibility in source types (*e.g.*, CAL3QHCR is unable to model certain types of projects or project features such as intermodal terminals or tunnels) and meteorological processing. Additionally, the Federal Aviation Administration (FAA) replaced CALINE3 with AERMOD in 2005 in its Emissions and Dispersion Modeling System (EDMS) to expand its capability and improve its accuracy in evaluating

airport impacts.<sup>15</sup> This, along with the fact that AERMOD has been used for many years already for PM hot-spot analyses for transportation conformity determinations, shows that AERMOD is more than capable of being useful for a wide variety of transportation projects and that the performance has been more than adequate for even the most complicated projects.

Comments were also made with respect to potential longer AERMOD model run times and the time necessary to set up model files and obtain meteorological data. These statements are not entirely reflective of the EPA's experience to date in implementing the PM hot-spot requirement. The EPA believes that AERMOD has been used for more complicated projects, since PM hot-spot analyses are completed for projects that are often very large and involve different project components that significantly increase the number of diesel vehicles. By their nature, these types of transportation projects involve more time to set up and complete and few transportation modelers have actually run both CAL3QHCR and AERMOD for equivalent projects.<sup>16</sup> In addition, volume sources have frequently been selected by implementers for AERMOD demonstrations, and this approach involves more time and effort in setting up the model runs, and more sources to be used than would be necessary with area sources. In addition, since AERMOD is already used in all 50 states for NSR purposes, meteorological input data for AERMOD are frequently prepared as a matter of course by the state and local air agencies and often made publicly available for download. Therefore, the EPA's understanding and experience is that the amount of time and resources necessary to create model inputs and complete PM hot-spot model simulations for AERMOD versus CAL3QHCR is not distinguishable from the overall process of running a traffic model, developing design alternatives for multiple purposes beyond conformity, and running the emissions model for the scenarios. In addition, as stated above and in the EPA's existing guidance, AERMOD has several advantages when conducting a PM hot-spot analysis: The ability to model a

<sup>15</sup> 70 FR 68218, Revision to the Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions, November 9, 2005.

<sup>16</sup> Quantitative PM hot-spot analyses are not required for most new projects in PM nonattainment and maintenance areas, and most state departments of transportation have not been required to complete such an analysis to date for transportation conformity.

<sup>14</sup> Heist, D., V. Isakov, S. Perry, M. Snyder, A. Venkatram, C. Hood, J. Stocker, D. Carruthers, S. Arunachalam, and R.C. Owen. Estimating near-road pollutant dispersion: A model inter-comparison. Transportation Research Part D: Transport and Environment. Elsevier BV, AMSTERDAM, Netherlands, 25:93-105, (2013).

variety of different transportation project types; the reliance on existing and more recent AERMET meteorological datasets obtained through the interagency consultation process; and additional capabilities that reduce the number of steps in conducting a PM hot-spot analyses.<sup>17</sup>

In response to the comments received and based on the analysis conducted by the EPA, the following actions are being taken in the final rulemaking:

- The EPA is replacing CALINE3 with AERMOD as the appendix A preferred model for refined modeling for mobile source applications. The EPA has reviewed the available literature and conducted its own analysis<sup>13</sup> that demonstrates AERMOD provides superior performance to that of CALINE3 for refined applications. The EPA emphasizes that AERMOD has been the only model that is applicable to all types of projects, including highway interchanges and intersections; transit, freight, and other terminal projects; intermodal projects; and projects in which nearby sources also need to be modeled.<sup>10</sup>

- The EPA acknowledges that the implementation of AERMOD for all refined modeling may take time, as many state transportation departments are not yet experienced with the AERMOD modeling system. Many states may have attended one of the EPA's multiple trainings but have not been involved in a quantitative PM hot-spot analysis to date. Thus, we are providing an extended 3-year transition period before AERMOD is required as the sole dispersion model for refined modeling in transportation conformity determinations. In addition, any refined analyses for which the air quality modeling was begun before the end of this 3-year period with a CALINE3-based model can be completed after the end of the transition period with that model, similar to the way the transportation conformity grace period for new emissions models is implemented.

- The EPA acknowledges that there are limited demonstrations of using AERMOD for multi-source screening and that additional development work is necessary to develop an AERMOD-based screening approach for CO that

satisfies the need for this type of analysis. Thus, we have modified section 4.2.3.1(b) of the *Guideline* to reference the EPA's 1992 CO guidance that employs CAL3QHC for CO screening analysis.<sup>12</sup> This technical guidance will remain in place as the recommended approach for CO screening until such time that the EPA (1) develops a new CO screening approach based on AERMOD or another appropriate model and (2) updates the *Guideline* to include the new CO screening approach. The use of CAL3QHC for CO screening does not need to undergo the review process discussed in the *Guideline* section 2.2(d). That review process is not necessary for CAL3QHC because its use is already well-established for CO hot-spot analyses and the review criteria have already been met.

- Finally, the EPA has formally recommended the establishment of a standing air quality modeling workgroup with the U.S. Department of Transportation, including the Federal Highway Administration, Federal Transit Administration, and FAA, to continue to evaluate and develop modeling practices for the transportation sector to ensure that future updates to dispersion models and methods reflect the latest available science and implementation.

See the docket for this action for the Response to Comments document for this part of the proposal as well as the EPA's latest technical support document (TSD) for using AERMOD for CO hot-spot screening analyses.

#### 5. Addressing Single-Source Impacts on Ozone and Secondary PM<sub>2.5</sub>

As discussed in our proposed action, on January 4, 2012, the EPA granted a petition submitted on behalf of the Sierra Club on July 28, 2010,<sup>18</sup> which requested that the EPA initiate rulemaking regarding the establishment of air quality models for ozone and PM<sub>2.5</sub> for use by all major sources applying for a PSD permit. In granting that petition, the EPA committed to engage in rulemaking to evaluate whether updates to the *Guideline* are warranted and, as appropriate, incorporate new analytical techniques or models for ozone and secondarily formed PM<sub>2.5</sub>. This final action completes the rulemaking process described in the EPA's granting of the

Sierra Club petition. As discussed in the proposal, the EPA has determined that advances in chemical transport modeling science indicate it is now reasonable to provide more specific, generally-applicable guidance that identifies particular models or analytical techniques that may be used under specific circumstances for assessing the impacts of an individual or single source on ozone and secondary PM<sub>2.5</sub>. For assessing secondary pollutant impacts from single sources, the degree of complexity required to appropriately assess potential impacts varies depending on the nature of the source, its emissions, and the background environment. In order to provide the user community flexibility in estimating single-source secondary pollutant impacts that allows for different approaches to credibly address these different areas, the EPA proposed a two-tiered demonstration approach for addressing single-source impacts on ozone and secondary PM<sub>2.5</sub>.

The first tier involves use of technically credible relationships between precursor emissions and a source's impacts that may be published in the peer-reviewed literature, developed from modeling that was previously conducted for an area by a source, a governmental agency, or some other entity and that is deemed sufficient, or generated by a peer-reviewed reduced form model. The second tier involves application of more sophisticated case-specific chemical transport models (CTMs) (e.g., photochemical grid models) to be determined in consultation with the EPA Regional Offices and conducted consistent with the EPA single-source modeling guidance.<sup>19</sup> The appropriate tier for a given application should be selected in consultation with the appropriate reviewing authority and be consistent with EPA guidance. We invited comments on whether our proposed two-tiered demonstration approach and related EPA technical guidance are appropriately based on sound science and practical application of available models and tools to address single-source impacts on ozone and secondary PM<sub>2.5</sub>.

Multiple commenters expressed support for the two-tiered approach for estimating single-source secondary impacts for permit-related programs, while other commenters did not support

<sup>17</sup> See Sections 7 and 9 of EPA's 2015 Transportation Conformity Guidance for Quantitative Hot-Spot Analyses in PM<sub>2.5</sub> and PM<sub>10</sub> Nonattainment and Maintenance Areas. For example, Exhibit 7-2 in this guidance highlights that AERMOD can be used for all project types that require PM hot-spot analyses under the transportation conformity rule, and Exhibit 7-3 clarifies the number of runs typically necessary for a PM hot-spot analysis with AERMOD (1-5 runs) versus CAL3QHCR (20 runs).

<sup>18</sup> U.S. Environmental Protection Agency, 2012. Sierra Club Petition Grant. Administrative Action dated January 4, 2012. U.S. Environmental Protection Agency, Washington, District of Columbia 20460. [https://www3.epa.gov/ttn/scram/10thmodconf/review\\_material/Sierra\\_Club\\_Petition\\_OAR-11-002-1093.pdf](https://www3.epa.gov/ttn/scram/10thmodconf/review_material/Sierra_Club_Petition_OAR-11-002-1093.pdf).

<sup>19</sup> U.S. Environmental Protection Agency, 2016. Guidance on the use of models for assessing the impacts of emissions from single sources on the secondarily formed pollutants ozone and PM<sub>2.5</sub>. Publication No. EPA 454/R-16-005. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

a multi-tiered approach for this purpose. Commenters also sought flexibility in the first tier to allow for area-specific demonstrations, thereby avoiding the second tier assessments where chemical transport modeling may be part of the demonstration. Most commenters support the idea of developing Model Emissions Rates for Precursors (MERPs) for use as a Tier 1 demonstration tool, as described in the preamble of the proposed rule. However, some commenters expressed the need for more specific information about Tier 1 demonstration tools, particularly MERPs. Furthermore, one commenter expressed concern about the particular use of demonstration tools, such as MERPs, not reflecting the combined ambient impacts across precursors and, in the context of PM<sub>2.5</sub>, in combining primary and secondary ambient impacts.

The EPA has issued draft guidance for use by permitting authorities and permit applicants and deferred rulemaking at this time to address how permitting authorities may develop and use significant impact levels (SILs) for ozone and PM<sub>2.5</sub>. In addition, we are not establishing a single set of national MERPs through rulemaking as we had anticipated in the preamble of the proposed rule. Instead, the EPA developed a draft technical guidance document to provide a framework for permitting authorities to develop area-specific MERPs consistent with the *Guidance on Significant Impact Levels for Ozone and Fine Particles in the Prevention of Significant Deterioration Permitting Program*.<sup>20</sup> Through this process, the EPA believes it has provided sufficient information regarding Tier 1 demonstration tools, such as MERPs. The draft MERPs technical guidance document<sup>21</sup> illustrates how permitting authorities may appropriately develop MERPs for specific areas and use them as a Tier 1 demonstration tool for permit-related programs. This draft guidance also explicitly addresses the commenter concern regarding the appropriate use of MERPs such that their use reflects the combined ambient impacts across precursors and, in the case of PM<sub>2.5</sub>, the combined primary and secondary

ambient impacts. This approach provides the flexibility requested by many commenters with respect to Tier 1 demonstration tools, such as MERPs, to generate information relevant for specific regions or areas rather than a single, national level that may not be representative of secondary formation in a particular region or area.

Specifically, the draft MERPs technical guidance provides information about how to use CTMs to estimate single-source impacts on ozone and secondary PM<sub>2.5</sub> and how these model simulation results can be used to develop empirical relationships for specific areas that may be appropriate as a Tier 1 demonstration tool. It also provides results from EPA photochemical modeling of multiple hypothetical situations across geographic areas and source types that may be used in developing MERPs consistent with the guidance or with supplemental modeling in situations where the EPA's modeling may not be representative. This flexible and scientifically credible approach allows for the development of area-specific Tier 1 demonstration tools that better represent the chemical and physical characteristics and secondary pollutant formation within that region or area.

The draft MERPs technical guidance<sup>21</sup> and the EPA's draft single-source modeling guidance<sup>19</sup> provide information to stakeholders about how to appropriately address the variety of chemical and physical characteristics regarding a project scenario and key receptor areas that should be addressed in conducting additional modeling to inform development of MERPs. The development of MERPs for ozone and secondary PM<sub>2.5</sub> precursors is just one example of a suitable Tier 1 demonstration tool. The EPA will continue to engage with the modeling community to identify credible alternative approaches for estimating single-source secondary pollutant impacts, which provide flexibility and are less resource intensive for permit demonstrations.

Commenters also stated that requiring chemical transport modeling as a Tier 2 demonstration tool places undue burden financially on the states, as they do not have the expertise to run or review such models, and that the regulated community does not have the expertise to run such models. Commenters requested a clearer rationale and procedure for applying CTMs for the purposes of estimating single-source secondary impacts for permit-related programs. In response, the EPA believes that its technical guidance on single-source modeling provides both the

clarity necessary to conduct such modeling and the flexibility appropriate to address such situations.

First, based on peer-reviewed assessments of models used for estimating ozone and secondary PM<sub>2.5</sub> for single-source impacts, the EPA continues to recommend that CTMs (including photochemical grid models or Lagrangian models) be used where a more refined Tier 2 demonstration for ozone or secondary PM<sub>2.5</sub> may be necessary. Given interest in the stakeholder community in different types of CTMs for the purposes of estimating single-source impacts for permit-related programs, and that these models, where applied appropriately, are fit for this purpose, selection of a single model for preferred status under the *Guideline* would impede sources from using a model or technique deemed most appropriate for specific situations, recognizing the diversity in chemical and physical environments across the United States.

Second, as discussed above, the EPA expects that the use of MERPs (or a similarly credible screening approach) as a Tier 1 demonstration tool will be sufficient for most sources to satisfy their compliance demonstration. For those situations where a refined Tier 2 demonstration is necessary, the EPA has provided detailed single-source modeling guidance with clear and credible procedures for estimating single-source secondary impacts from sources doing permit related assessments. The EPA has future plans to provide a module as part of its *Software for Model Attainment Test (SMAT)* tool, a publicly available, Windows-based program, that will allow users to work with output generated from CTMs to provide a consistent approach for estimating single-source ozone or secondary PM<sub>2.5</sub> impacts consistent with EPA guidance and the *Guideline*.

Multiple commenters do not agree that photochemical grid models can adequately assess single-source impacts. A commenter recognized that photochemical grid model evaluations using in-plume traverses are encouraging as documented in the IWAQM reports, but stated that more work is needed to generate additional confidence in the technique, and further requests that the EPA use newer field study data from 2013 to evaluate CTM performance against in-plume transects of ozone and secondary PM<sub>2.5</sub>.

As referenced in the preamble to the proposal, the EPA has relied upon extensive peer-reviewed literature showing that photochemical grid models have been applied for single-

<sup>20</sup> U.S. Environmental Protection Agency, 2016. *Guidance on Significant Impact Levels for Ozone and Fine Particles in the Prevention of Significant Deterioration Permitting Program*. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

<sup>21</sup> U.S. Environmental Protection Agency, 2016. *Guidance on the Use of Modeled Emission Rates for Precursors (MERPs) as a Tier 1 Demonstration Tool for Permit Related Programs*. Publication No. EPA 454/R-16-006. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

source impacts and, compared with near-source downwind in-plume measurements, that the models adequately represent secondary pollutant impacts from a specific facility. The literature shows that these models can clearly differentiate impacts of a specific facility from those of other sources.<sup>22 23</sup> Other peer-reviewed research has clearly shown that photochemical grid models are able to simulate impacts from single sources on secondarily-formed pollutants.<sup>24 25 26</sup> Further, single-source secondary impacts have been provided in technical reports that further support the utility of these tools for single-source scientific and regulatory assessments.<sup>27 28 29</sup> The EPA firmly believes that the peer-reviewed science clearly demonstrates that photochemical grid models can adequately assess single-source impacts. The EPA recognizes that ongoing evaluations in this area that will lead to continual improvements in the applicability of these models, such as the work underway to compare photochemical grid model estimates of single-source impacts with in-plume aircraft measurements made as part of the 2013 SENEX field campaign.<sup>30</sup>

<sup>22</sup> Baker, K.R., Kelly, J.T., 2014. Single Source Impacts Estimated with Photochemical Model Source Sensitivity and Apportionment Approaches. *Atmospheric Environment* 96, 266–274.

<sup>23</sup> Zhou, W., Cohan, D.S., Pinder, R.W., Neuman, J.A., Holloway, J.S., Peischl, J., Ryerson, T.B., Nowak, J.B., Flocke, F., Zheng, W.G., 2012. Observation and Modeling of the Evolution of Texas Power Plant Plumes. *Atmospheric Chemistry and Physics* 12, 455–468.

<sup>24</sup> Baker, K.R., Kotchenruther, R.A., Hudman, R.C., 2015. Estimating Ozone and Secondary PM<sub>2.5</sub> Impacts from Hypothetical Single Source Emissions in the Central and Eastern United States. *Atmospheric Pollution Research* 7, 122–133.

<sup>25</sup> Bergin, M.S., Russell, A.G., Odman, M.T., Cohan, D.S., Chameldes, W.L., 2008. Single-Source Impact Analysis Using Three-Dimensional Air Quality Models. *Journal of the Air & Waste Management Association* 58, 1351–1359.

<sup>26</sup> Kelly, J.T., Baker, K.R., Napelenok, S.L., Roselle, S.J., 2015. Examining Single-Source Secondary Impacts Estimated from Brute-force, Decoupled Direct Method, and Advanced Plume Treatment Approaches. *Atmospheric Environment* 111, 10–19.

<sup>27</sup> ENVIRON, 2012a. Comparison of Single-Source Air Quality Assessment Techniques for Ozone, PM<sub>2.5</sub>, other Criteria Pollutants and AQRVs, EPA Contract No: EP–D–07–102. September 2012. 06–20443M6.

<sup>28</sup> ENVIRON, 2012b. Evaluation of Chemical Dispersion Models Using Atmospheric Plume Measurements from Field Experiments, EPA Contract No: EP–D–07–102. September 2012. 06–20443M6.

<sup>29</sup> Yarwood, G., Scorgie, Y., Agapides, N., Tai, E., Karamchandani, P., Duc, H., Trieu, T., Bawden, K., 2011. Ozone Impact Screening Method for New Sources Based on High-order Sensitivity Analysis of CAMx Simulations for NSW Metropolitan Areas.

<sup>30</sup> National Oceanic & Atmospheric Administration. Southeast Nexus (SENEX) 2013. Studying the Interactions Between Natural and Anthropogenic Emissions at the Nexus of Climate

Commenters requested that the EPA consider Lagrangian CTMs for use in assessing single-source secondary impacts. A commenter proposed that the Second-order Closure Integrated Puff Model (SCICHEM) can provide an alternative modeling platform for all single-source regulatory applications including ozone and secondary PM<sub>2.5</sub> impacts. Commenters note that SCICHEM does not suffer from limitations of other Lagrangian puff models with respect to overlapping puffs having similar access to background species as noted in the EPA's single-source modeling guidance.

The proposed revisions to the *Guideline* and EPA's single-source modeling guidance clearly indicate that CTMs are appropriate for estimating single-source impacts on ozone and secondary PM<sub>2.5</sub> as a Tier 2 demonstration tool or as means to develop a Tier 1 demonstration tool. Both Lagrangian puff models and photochemical grid models may be appropriate for this purpose where those models fulfill alternative model criteria detailed in section 3.2.2 of the *Guideline*. Furthermore, the single-source modeling guidance has been updated to reflect the difference in treatment of overlapping puffs and background in SCICHEM compared to other Lagrangian puff models. However, the EPA believes photochemical grid models are generally most appropriate for addressing ozone and secondary PM<sub>2.5</sub> because they provide a spatially and temporally dynamic realistic chemical and physical environment for plume growth and chemical transformation.<sup>33 34</sup> Publicly available and documented Eulerian photochemical grid models such as the Comprehensive Air Quality Model with Extensions (CAMx)<sup>31</sup> and the Community Multiscale Air Quality (CMAQ)<sup>32</sup> model treat emissions, chemical transformation, transport, and deposition using time and space variant meteorology. These modeling systems include primarily emitted species and secondarily formed pollutants such as ozone and PM<sub>2.5</sub>.<sup>33 34 35 36</sup> In addition,

Change and Air Quality. <http://www.esrl.noaa.gov/csd/projects/senex>.

<sup>31</sup> ENVIRON, 2014. User's Guide Comprehensive Air Quality Model with Extensions version 6, <http://www.camx.com>. ENVIRON International Corporation, Novato.

<sup>32</sup> Byun, D., Schere, K.L., 2006. Review of the Governing Equations, Computational Algorithms, and Other Components of the Models-3 Community Multiscale Air Quality (CMAQ) modeling system. *Applied Mechanics Reviews*, 59: 51–77.

<sup>33</sup> Chen, J., Lu, J., Avise, J.C., DaMassa, J.A., Kleeman, M.J., Kaduwela, A.P., 2014. Seasonal Modeling of PM<sub>2.5</sub> in California's San Joaquin Valley. *Atmospheric Environment*, 92: 182–190.

these models have been used extensively to support ozone and PM<sub>2.5</sub> SIPs and to explore relationships between inputs and air quality impacts in the United States and elsewhere.<sup>23 37 38</sup>

The EPA is promulgating the two-tiered demonstration approach as described in section 5 of the *Guideline* and updating EPA technical guidance that was released at the time of proposal in response to public comments. These revisions to the *Guideline* and supporting technical guidance are based on sound science and practical application of available models and tools to address single-source impacts on ozone and secondary PM<sub>2.5</sub>. In particular, the EPA has updated its previous PM<sub>2.5</sub> modeling guidance for permitting<sup>39</sup> to reflect these changes and also incorporated appropriate sections for ozone in releasing its *Guidance for Ozone and PM<sub>2.5</sub> Permit Modeling*<sup>40</sup> with this final rule.

## 6. Status of CALPUFF and Assessing Long-Range Transport for PSD Increments and Regional Haze

The EPA proposed a screening approach to address long-range transport for purposes of assessing PSD increments, its decision to remove CALPUFF as a preferred model in appendix A for such long-range transport assessments, and its decision

<sup>34</sup> Civerolo, K., Hogrefe, C., Zalewsky, E., Hao, W., Sistla, G., Lynn, B., Rosenzweig, C., Kinney, P.L., 2010. Evaluation of an 18-year CMAQ Simulation: Seasonal Variations and Long-term Temporal Changes in Sulfate and Nitrate. *Atmospheric Environment*, 44: 3745–3752.

<sup>35</sup> Russell, A.G., 2008. EPA Supersites Program-related Emissions-based Particulate Matter Modeling: Initial Applications and Advances. *Journal of the Air & Waste Management Association*, 58: 289–302.

<sup>36</sup> Tesche, T., Morris, R., Tonnesen, G., McNally, D., Boylan, J., Brewer, P., 2006. CMAQ/CAMx Annual 2002 Performance Evaluation Over the Eastern US. *Atmospheric Environment*, 40: 4906–4919.

<sup>37</sup> Cai, C., Kelly, J.T., Avise, J.C., Kaduwela, A.P., Stockwell, W.R., 2011. Photochemical Modeling in California with Two Chemical Mechanisms: Model Intercomparison and Response to Emission Reductions. *Journal of the Air & Waste Management Association*, 61: 559–572.

<sup>38</sup> Hogrefe, C., Hao, W., Zalewsky, E., Ku, J.-Y., Lynn, B., Rosenzweig, C., Schultz, M., Rast, S., Newchurch, M., Wang, L., 2011. An Analysis of Long-term Regional-scale Ozone Simulations Over the Northeastern United States: Variability and Trends. *Atmospheric Chemistry and Physics*, 11: 567–582.

<sup>39</sup> U.S. Environmental Protection Agency, 2014. Guidance for PM<sub>2.5</sub> Modeling. May 20, 2014. Publication No. EPA–454/B–14–001. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

<sup>40</sup> U.S. Environmental Protection Agency, 2016. Guidance for Ozone and PM<sub>2.5</sub> Permit Modeling. Publication No. EPA–454/B–16–005. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

to consider CALPUFF as a screening technique along with other Lagrangian models to be used in consultation with the appropriate reviewing authority. In order to provide the user community flexibility in estimating single-source secondary pollutant impacts and given the availability of more appropriate modeling techniques, such as photochemical grid models (which address limitations of models like CALPUFF<sup>41</sup>), the EPA proposed that the *Guideline* no longer contain language that requires the use of CALPUFF or another Lagrangian puff model for long-range transport assessments. The EPA did recognize that long-range transport assessments may be necessary in certain limited situations for PSD increments, particularly for Class I areas. For these situations, the EPA proposed a screening approach where CALPUFF, along with other appropriate screening tools and methods, may be used to support long-range transport assessments of PSD increments.

We received comment that there may also be certain situations where long-range transport assessments of NAAQS compliance may be necessary because either near-field NAAQS compliance is not required or the nearest receptors of concern are greater than 50 km (e.g., many Outer Continental Shelf sources). We agree with this comment and are amending the proposed screening approach in section 4.2 of the *Guideline* to also include a long-range assessment of NAAQS compliance, when appropriate. Specifically, to determine if NAAQS or PSD increments analyses may be necessary beyond 50 km (i.e., long-range transport assessment), the EPA is updating its recommended screening approach to cases where near-field NAAQS compliance is not required or the nearest receptors of concern are greater than 50 km away.

Some commenters also expressed concern about the appropriateness of the EPA's technical basis for establishing the long-range transport screening assessment and, in particular, the appropriateness of the ambient levels used as benchmarks for evaluating the hypothetical source impacts. To support the EPA's proposed approach for long-range transport, we provided a TSD that demonstrated the level of single-source impacts from a

variety of facility types.<sup>42</sup> The facility impacts were compared to benchmark ambient values for NO<sub>2</sub>, SO<sub>2</sub>, PM<sub>10</sub>, and PM<sub>2.5</sub> in order to determine which facility types and pollutants might have impacts above these levels at 50 km from the source. The comments on the proposal indicated confusion about which values were applied in the TSD and, in particular, confusion about values used for Class I areas for both NAAQS and PSD increments. The EPA believes that because each NAAQS is uniform throughout the class areas, no class-specific protection is necessary when assessing whether a source causes or contributes to a violation of the NAAQS. Thus, for all NAAQS analyses, a uniform set of benchmark ambient values were used in the TSD across all class areas. However, the EPA recognizes that, historically, Congress has provided special protections to Class I areas, via more protective PSD increments. Thus, for all PSD increments analyses detailed in the TSD, more conservative benchmark ambient values applicable to Class I areas for PSD increments were used. The EPA has updated the TSD to more clearly reflect these conditions and alleviate the confusion on behalf of the commenters. These modifications do not affect the results or conclusions from the analysis or the finalization of the EPA's approach for long-range transport screening.

A number of commenters expressed concern about the EPA's proposed removal of CALPUFF as the preferred long-range transport model in appendix A and do not support its removal without replacement. Other commenters indicated that a lack of an EPA-preferred long-range transport model increases uncertainty in performing Class I PSD increment analyses or could lead to inconsistent modeling approaches for such analyses. Also, many of these same commenters expressed concerns about the need for its approval as an alternative model and the additional time that such a process would entail.

The EPA has presented a well-reasoned and technically sound screening approach for long-range transport assessments for NAAQS and PSD increments that streamlines the time and resources necessary to conduct such analyses and provides for appropriate flexibility in the use of CALPUFF or other Lagrangian models

as a screening technique. To address concerns by commenters related to the approval of CALPUFF or other Lagrangian model in this screening approach, the EPA has modified section 4.2.1 of the *Guideline* to specifically recognize the use of Lagrangian models as an appropriate screening technique, for this purpose, that does not need to be approved by the EPA as an alternative model. Rather, the selection of specific model and model parameters must be done in consultation with the appropriate reviewing authority and EPA Regional Office. We consider the flexibility in selection of the appropriate screening technique provided by this long-range screening approach to be critically important for applicants to apply the most suitable technical basis to inform these complex situations. To the extent that a cumulative impact analysis is necessary at distances beyond 50 km, then the use of a Lagrangian or other model is subject to approval under section 3.2.2(e) of the *Guideline*. In response to commenter concerns about the additional time and potential delays associated with such approvals, as discussed in more detail later in this preamble, the EPA disagrees with such contentions and notes that the recently observed average response time of MCH concurrences on alternative models is less than a month.

Some commenters also stated that the EPA had not provided sufficient scientific or technical justification for removal of CALPUFF in appendix A, while other commenters supported the removal of CALPUFF as a preferred model. One commenter provided detailed information documenting the inconsistent nature of CALPUFF performance to more fully support the EPA's proposed action to remove it as a preferred model. As detailed in the Response to Comments document, the EPA has fully documented the past and current concerns related to the regulatory use of the CALPUFF modeling system and believes that these concerns, including the well-documented scientific and technical issues with the modeling system, support the EPA's decision to remove it as a preferred model in appendix A of the *Guideline*. In addition, there was no substantive or technical information submitted in the public comments that would lead the EPA to reconsider its documented concerns about the CALPUFF modeling system and its regulatory use.

In addition, a few commenters recommended that the EPA consider Lagrangian CTMs to address long-range transport from single sources. In this regard, some commenters mentioned the

<sup>41</sup> U.S. Environmental Protection Agency, 2016. Reassessment of the Interagency Workgroup on Air Quality Modeling Phase 2 Summary Report; Revisions to Phase 2 Recommendations. Publication No. EPA-454/R-16-007. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

<sup>42</sup> U.S. Environmental Protection Agency, 2015. Technical Support Document (TSD) for AERMOD-Based Assessments of Long-Range Transport Impacts for Primary Pollutants. Publication No. EPA-454/B-15-003. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

more advanced version of CALPUFF for consideration here and specifically proposed that the SCICHEM model can also provide an alternative modeling platform for all single-source regulatory applications including ozone and secondary PM<sub>2.5</sub> impacts. In addition, they noted that SCICHEM does not suffer from limitations of other Lagrangian puff models with respect to overlapping puffs having similar access to background species as noted in the EPA's single-source modeling guidance. While the information provided by commenters is not sufficient for the EPA to adopt a replacement to CALPUFF as an appendix A model for long-range transport, this information clearly indicates that there are other models available and potentially suitable for use in these situations. Given the EPA's determination regarding the appropriateness of using current models and tools to address single-source impacts on ozone and secondary PM<sub>2.5</sub>, we will continue to work with the modeling community on the development and evaluation of models that may be suitable for future consideration as preferred models to meet long-range assessment needs, as well as broader use in demonstrating compliance with NAAQS and PSD increments. Such developments would further strengthen the scientific credibility of the models and approaches used under the *Guideline* and continue to streamline their regulatory application through use of integrated models with capabilities to address multiple pollutants.

As previously noted in the proposed rule, Phase 3 of the IWAQM process was reinitiated in June 2013 to further the EPA's commitment to update the *Guideline* to address chemically reactive pollutants in near-field and long-range transport applications. This Phase 3 effort included the establishment of a workgroup composed of EPA and Federal Land Managers (FLM) technical staff focused on long-range transport of primary and secondary pollutants with an emphasis on use of consistent approaches to those being developed and applied to meet near-field assessment needs for ozone and secondarily-formed PM<sub>2.5</sub>. The EPA expects that such approaches will be focused on state-of-the-science CTMs as detailed in IWAQM reports<sup>43 44</sup> and published literature.

<sup>43</sup> U.S. Environmental Protection Agency, 2015. Interagency Workgroup on Air Quality Modeling Phase 3 Summary Report: Near-Field Single Source Secondary Impacts. Publication No. EPA 454/P-15-002. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

To inform future consideration of visibility modeling in regulatory applications consistent with the EPA's guidance for addressing chemistry for single-source impact on ozone and secondary PM<sub>2.5</sub>, the final report<sup>44</sup> of the IWAQM long-range transport subgroup identified that modern CTMs have evolved sufficiently and provide a credible platform for estimating potential visibility impacts from a single or small group of emission sources. Such CTMs are well suited for the purpose of estimating long-range impacts of secondary pollutants, such as PM<sub>2.5</sub>, that contribute to regional haze and other secondary pollutants, such as ozone, that contribute to negative impacts on vegetation through deposition processes. These multiple needs require a full chemistry photochemical model capable of representing gas, particle, and aqueous phase chemistry for PM<sub>2.5</sub>, haze, and ozone.

Photochemical grid models are suitable for estimating visibility and deposition since important physical and chemical processes related to the formation and transport of PM are realistically treated. Source sensitivity and apportionment techniques implemented in photochemical grid models have evolved sufficiently and provide the opportunity for estimating potential visibility and deposition impacts from one or a small group of emission sources using a full science photochemical grid model. Photochemical grid models using meteorology output from prognostic meteorological models have demonstrated skill in estimating source-receptor relationships in the near-field<sup>24 27</sup> and over long distances.<sup>45</sup>

Photochemical grid models have been shown to demonstrate similar skill to Lagrangian models for pollutant transport when compared to measurements made from multiple mesoscale field experiments.<sup>45</sup> Use of CTMs for Air Quality Related Values (AQRV) analysis requirements, while not subject to specific EPA model approval requirements outlined in 40 CFR 51.166(l)(2) and 40 CFR 52.21(l)(2), should be justified for each application following the general recommendations

<sup>44</sup> U.S. Environmental Protection Agency, 2015. Interagency Workgroup on Air Quality Modeling Phase 3 Summary Report: Long Range Transport and Air Quality Related Values. Publication No. EPA 454/P-15-003. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

<sup>45</sup> ENVIRON, 2012. Documentation of the Evaluation of CALPUFF and Other Long Range Transport Models using Tracer Field Experiment Data, EPA Contract No: EP-D-07-102. February 2012. 06-20443M4. [https://www3.epa.gov/ttn/scram/reports/EPA-454\\_R-12-003.pdf](https://www3.epa.gov/ttn/scram/reports/EPA-454_R-12-003.pdf).

outlined in section 3.2.2 of the *Guideline*, and concurrence sought with the affected FLM(s).

As proposed, with revisions discussed above, we are taking final action to codify the screening approach to address long-range transport for purposes of assessing NAAQS and/or PSD increments; removing CALPUFF as a preferred model in appendix A for such long-range transport assessments; and confirming our recommendation to consider CALPUFF as a screening technique along with other Lagrangian models that may be used as part of this screening approach without alternative model approval. As detailed in the preamble of the proposed rule, it is important to note that the EPA's final action to remove CALPUFF as a preferred appendix A model in this *Guideline* does not affect its use under the FLM's guidance regarding AQRV assessments (FLAG 2010) nor any previous use of this model as part of regulatory modeling applications required under the CAA. Similarly, this final action does not affect the EPA's recommendation that states use CALPUFF to determine the applicability and level of best available retrofit technology in regional haze implementation plans.<sup>46</sup> It is also important to note that the use of CALPUFF in the near-field as an alternative model for situations involving complex terrain and complex winds is not changed by removal of CALPUFF as a preferred model in appendix A. The EPA recognizes that AERMOD, as a Gaussian plume dispersion model, may be limited in its ability to appropriately address such situations, and that CALPUFF or other Lagrangian model may be more suitable, so we continue to provide the flexibility of alternative model approvals (as has been in place since the 2003 revisions to the *Guideline*).

#### 7. Role of EPA's Model Clearinghouse (MCH)

We proposed to codify our existing practice of requiring consultation and coordination between the EPA Regional Offices and the EPA's MCH on all approvals (under section 3.2.2 of the *Guideline*) of alternative models or techniques. This coordination process has been in practice for almost three decades during which the MCH has served a critical role in helping resolve issues that have arisen from unique situations that were not specifically addressed in the *Guideline* or necessitated the consideration of an alternative model or technique for a

<sup>46</sup> See 70 FR 39104, 39122-23 (July 6, 2005).

specific application or range of applications. However, the most comprehensive documentation of this coordination process was a 1988 EPA memorandum to the EPA Regional Offices defining the Model Clearinghouse Operational Plan,<sup>47</sup> which was not widely available to the regulated modeling community until it is included in the docket for the proposed rule. In response to the proposal and docketed information, the EPA received a wide range of comments regarding the MCH and the related proposed revisions to the *Guideline*.

The majority of the commenters expressed varying levels of concern with the potential for significant delay to the permit review process if all the EPA Regional Office alternative model approvals were required to seek concurrence from the MCH. Several commenters suggested that the current process, as defined in the existing *Guideline*, is appropriate and should not be changed. Other commenters stated that the current MCH process is slow, cumbersome, and in many ways, not needed. Certain industry commenters recommended the establishment of specific timeline requirements for the EPA Regional Office and MCH alternative model approvals. Other industry comments recommended the establishment of an external review committee for alternative model approvals and/or an external advisory group to recommend additional changes to the MCH process. Finally, there were a few comments expressing concern that the MCH process is not well-known and that decisions by the MCH are not widely disseminated.

With regard to comments about possible delay to the approval process for an alternative model, it is important to point out that the revisions to the *Guideline* are only codifying an existing process between the EPA Regional Offices and the Model Clearinghouse. Therefore, the administrative processing time for these approvals should not be affected by codifying the existing process. In fact, we anticipate that this action will further streamline the process by clarifying it for the regulatory modeling community. Additionally, the revisions will ensure fairness, consistency, and transparency in modeling decisions across all EPA Regional Offices. Additional important aspects of these revisions were noted and supported through comment by several state air permitting agencies, an

organization representing the state agencies, and a large industrial trade organization.

It is important to note that the EPA's MCH has formally accepted and concurred with five alternative model requests from the EPA Regional Offices since proposal of this rule. The average MCH response time for those five requests was 28 days. There was some variability in the timing of these formal concurrences with one of the concurrences being completed within less than a day; three of the concurrences taking approximately 22 days; and one of the more complex requests taking slightly longer than 2 months. The range of MCH response times over the past year is indicative of applicants that have either engaged early with their respective EPA Regional Office through vetting of a modeling protocol and the identification and coordination of significant issues prior to submittal of their modeling compliance demonstration, or applicants that have performed a substantial amount of modeling work and justification documentation prior to any engagement with the EPA Regional Office or MCH.

When applicants do not engage with the EPA early in the process, additional time is often needed for the justification of the alternative model or options selected and/or remodeling of their facility based on issues realized through review by the EPA. In a few cases, the approach desired by an applicant had to be completely reworked from the beginning, which created significant delays in the permit review and approval process. Early engagement with the EPA will result in the shortest amount of time needed for any alternative model approval by the Agency. However, complex situations involving facilities with unique issues, and requesting a completely new or novel alternative model approach, will require additional time for the applicant, the appropriate reviewing authority, the EPA Regional Office, and the EPA's MCH to collaboratively work together through an informed and iterative process to achieve an approvable alternative model submittal. For these reasons and the recently observed response time of MCH concurrences on alternative models of less than a month, we believe that it is unwarranted to impose a regulatory time limit on the MCH concurrence process. The revised Model Clearinghouse Operational Plan outlines the MCH process by defining the roles and responsibilities of all parties, providing thorough descriptions and flow diagrams, referencing the current

databases that store all formal MCH decisions, making available templates for request memoranda and other pertinent information, and providing "best practice" examples of request memoranda that highlight how to best inform the MCH process. We believe these enhancements will increase clarity and understanding of this process and make the imposition of a regulatory time limit unnecessary. This Model Clearinghouse Operational Plan is included in the docket and available on the EPA's SCRAM Web site.

The suggestion by commenters to use an external review committee for alternative model approvals is unnecessary and inappropriate. The CAA requires that air quality models are specified by the EPA Administrator. Any modification or substitution of a regulatory model under the *Guideline* can only be made with written approval of the Administrator. The delegation of this preferred model or alternative model approval process can only occur within the EPA. Also, an external review committee would add another layer of review and coordination to the prerequisite EPA processes and would ultimately result in delays in the overall permit review and approval process. Aside from future regulatory revisions of the *Guideline*, the EPA is required per CAA section 320 to conduct a Conference on Air Quality Modeling at least every 3 years, at which time formal public comment on the MCH process or any other aspect of the *Guideline* can be provided. The EPA believes that the current process demonstrates our continued commitment to provide the regulatory community with scientifically credible models and techniques developed through collaborative efforts, which are provided in updates to the *Guideline*.

In this action, as proposed, we are codifying the long-standing process of the EPA Regional Offices consulting and coordinating with the MCH on all approvals of alternative models or techniques. While the Regional Administrators are the delegated authority to issue such approvals under section 3.2.2 of the *Guideline*, all alternative model approvals will be issued only after consultation with the EPA's MCH and formal documentation through a concurrence memorandum that indicates that the alternative model requirements in section 3.2.2 have been met.

#### 8. Updates to Modeling Procedures for Cumulative Impact Analysis

As discussed in the preamble to our proposed action, based on input from the Tenth Modeling Conference and

<sup>47</sup> U.S. Environmental Protection Agency, 2016. Model Clearinghouse: Operational Plan. Publication No. EPA-454/B-16-008. Office of Air Quality Planning and Standards, Research Triangle Park, NC.



recent permit modeling experiences under the 1-hour NAAQS for SO<sub>2</sub> and NO<sub>2</sub>, we proposed revisions in section 8 of the *Guideline* and associated guidance to provide the necessary clarification in selecting and establishing the model domain and inputs for conducting the regulatory modeling for PSD and SIP applications. In addition to solicited public feedback on section 8, we received numerous public comments with respect to section 9 of the *Guideline*, which is revised to more clearly summarize the general concepts represented throughout the *Guideline* and set the stage for appropriate regulatory application of models and/or, in rare circumstance, air quality monitoring data.

Many of these revisions are based on the EPA clarification memoranda issued since 2010 that were intended to provide the necessary clarification regarding applicability of the *Guideline* to PSD modeling for these new standards.<sup>48 49 50 51</sup> The EPA has specifically cautioned against the literal and uncritical application of very prescriptive procedures for conducting NAAQS and PSD increments modeling compliance demonstrations as described in chapter C of the 1990 draft New Source Review Workshop Manual.<sup>52</sup> Following such procedures in a literal and uncritical manner has led to

practices that are overly conservative and unnecessarily complicate the permitting process.

Commenters were supportive of the addition of the definition of the modeling domain, including the appropriate factors to consider, for NAAQS and PSD increments assessments and for SIP attainment demonstrations in section 8 of the *Guideline*. However, several commenters stated that the discussion in the proposed *Guideline* could result in conservatively large modeling domains regularly extending to 50 km. A typographical error was identified in that discussion that may have caused this confusion and is corrected in this final rule. With this correction, it is now clear that the modeling domain or proposed project's impact area is defined as an area with a radius extending from the new or modifying source to: (1) The most distant location where air quality modeling predicts a significant ambient impact will occur, or (2) the nominal 50 km distance considered applicable for Gaussian dispersion models, whichever is *less* [emphasis added]. In most situations, the extent to which a significant ambient impact could occur from a new or modifying source likely will be considerably less than 50 km.

Commenters also were supportive of the expanded discussion of receptor sites in section 9 of the *Guideline*. There were several requests for additional considerations for the potential exclusion of receptors from the modeling domain based on various factors. Along these lines, a few commenters requested that we add a formal definition of "ambient air" into the *Guideline* and provide specific exceptions to allow for the exclusion of certain receptors. The definition of "ambient air" and related provisions are provided in 40 CFR 50.1(e). Principles for justifying exclusion of particular areas from this definition of "ambient air" are discussed in EPA guidance for the PSD program. The EPA has not proposed to revise this definition or how the EPA has interpreted it in guidance. Thus, we do not believe it is necessary to address this topic within the *Guideline*.

There was overwhelming support by the stakeholder community for revisions to the *Guideline* that would bring additional clarity and flexibility concerning the process of determining background concentrations used in constructing the design concentration, or total air quality concentration, as a part of a cumulative impact analysis for NAAQS and PSD increments. There were, however, numerous specific

public comments highlighting typographical errors or requesting additional clarifications on particular details of this process. Where appropriate, revisions were made to the *Guideline* to address many of these comments. A few of the public comments identified concerns that we have already addressed within other portions of the *Guideline* or desired more technical detail than is necessary in regulatory text and are best addressed through updates to existing technical guidance.

In particular, there were numerous requests to further clarify the analysis of significant concentration gradients from "nearby sources," as used in the selection of which nearby sources should be explicitly modeled in a cumulative impact assessment under PSD. In the proposed revisions to the *Guideline*, we expanded the concept of significant concentration gradients from the previous version of the *Guideline*. Given the uniqueness of each modeling situation and the large number of variables involved in identifying nearby sources, we continue to believe that comprehensively defining significant concentration gradients in the *Guideline* is inappropriate and could be unintentionally and excessively restrictive. Rather, the identification of nearby sources to be explicitly modeled is regarded as an exercise of professional judgment to be accomplished jointly by the applicant and the appropriate reviewing authority. Following this final action, we will continue to work with the stakeholder community to clarify and improve upon the existing technical guidance and associated approaches that could be used to develop and analyze significant concentrations gradients from nearby sources.

We received numerous comments from the stakeholder community supporting the proposed revisions to Tables 8–1 and 8–2 that allow for the modeling of nearby sources using a representation of average actual emissions based on the most recent 2 years of normal source operation. Typographical errors were noted in the public comments and have subsequently been corrected in both of these tables. The public comments also include additional recommendations for alternate procedures to develop or calculate actual emissions; however, these commenters either did not include substantive technical support for these recommendations or they were inconsistent with the required application of the preferred appendix A model.

<sup>48</sup> U.S. Environmental Protection Agency, 2010. Applicability of Appendix W Modeling Guidance for the 1-hour NO<sub>2</sub> NAAQS. Memorandum dated June 28, 2010, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scram/guidance/clarification/ClarificationMemo\\_AppendixW\\_Hourly-NO2-NAAQS\\_FINAL\\_06-28-2010.pdf](https://www3.epa.gov/ttn/scram/guidance/clarification/ClarificationMemo_AppendixW_Hourly-NO2-NAAQS_FINAL_06-28-2010.pdf).

<sup>49</sup> U.S. Environmental Protection Agency, 2010. Applicability of Appendix W Modeling Guidance for the 1-hour SO<sub>2</sub> NAAQS. Memorandum dated August 23, 2010, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scram/guidance/clarification/ClarificationMemo\\_AppendixW\\_Hourly-SO2-NAAQS\\_FINAL\\_08-23-2010.pdf](https://www3.epa.gov/ttn/scram/guidance/clarification/ClarificationMemo_AppendixW_Hourly-SO2-NAAQS_FINAL_08-23-2010.pdf).

<sup>50</sup> U.S. Environmental Protection Agency, 2011. Additional Clarification Regarding Applicability of Appendix W Modeling Guidance for the 1-hour NO<sub>2</sub> NAAQS. Memorandum dated March 1, 2011, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scram/guidance/clarification/Additional\\_Clarifications\\_AppendixW\\_Hourly-NO2-NAAQS\\_FINAL\\_03-01-2011.pdf](https://www3.epa.gov/ttn/scram/guidance/clarification/Additional_Clarifications_AppendixW_Hourly-NO2-NAAQS_FINAL_03-01-2011.pdf).

<sup>51</sup> U.S. Environmental Protection Agency, 2014. Clarification on the Use of AERMOD Dispersion Modeling for Demonstrating Compliance with the NO<sub>2</sub> National Ambient Air Quality Standard. Memorandum dated September 30, 2014, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scram/guidance/clarification/NO2\\_Clarification\\_Memo-20140930.pdf](https://www3.epa.gov/ttn/scram/guidance/clarification/NO2_Clarification_Memo-20140930.pdf).

<sup>52</sup> U.S. Environmental Protection Agency, 1990. New Source Review Workshop Manual: Prevention of Significant Deterioration and Nonattainment Area Permitting (Draft). Office of Air Quality Planning and Standards, Research Triangle Park, NC. <https://www.epa.gov/nsr>.

Several commenters from the industrial sector suggested that the *Guideline* should be further amended to allow modeling approaches that account for emissions variability in NSR permitting for new and modifying sources. Additionally, there was public comment that highly intermittent sources should be categorically excluded from NAAQS assessments for statistically-based short-term standards. The emissions variability approaches and exclusion of highly intermittent sources would be a significant departure from long-standing EPA policy in the NSR program and are not addressed in the *Guideline*. If there are future revisions to the NSR program that would allow for such considerations, then appropriate revisions to the *Guideline* would be considered at that time.

A few public comments expressed concern with our recommendation of using the current monitored design value as the background ambient concentration to be included with any explicitly modeled nearby sources and the estimated modeled impact of the source for comparison to the appropriate NAAQS in PSD assessments. The concern expressed in the comments is that this practice is exceedingly conservative and results in very unrealistic characterizations of the design concentration. We agree that certain combinations of monitored background data and modeled concentrations can lead to overly conservative assessments. However, we also point out that section 8.3.2(c) of the *Guideline* clearly states that the best starting point for many cases is the use of the current design value, but there are many cases in which the current design value may not be appropriate. We then provide four example cases where the use of the current monitored design value is not appropriate and further state that this list of examples is not exhaustive such that other cases could be considered on a case-by-case basis with approval by the appropriate reviewing authority.

The modeling protocols discussion at the beginning of section 9 of the *Guideline* received a few public comments. One commenter wanted the discussion to be less prescriptive and not require involvement of the EPA Regional office for every protocol. Another commenter wanted the EPA to establish specific deadlines for approvals (or disapprovals) of modeling protocols. We are aware that the discussion on modeling protocols does not contain any specific requirements for applicants or permit reviewing authorities. Rather, the modeling

protocol discussion is provided to recommend best practices to streamline the regulatory modeling process and avoid unnecessary work and additional permit delays. Given the added complexity of the technical issues that arise in the context of demonstrating regulatory compliance through air quality modeling, we strongly encourage the development of comprehensive modeling protocols by the applicants and a thorough vetting of these protocols by the appropriate reviewing authority prior to the start of any work on a project. In circumstances where alternative models or non-*Guideline* procedures are being considered, it is advisable to also include the EPA Regional Office in the initial protocol meeting if it is not the primary permit reviewing authority.

Finally, there were a few general comments on the discussion of NAAQS and PSD increments compliance demonstrations within section 9 of the *Guideline*. Some of those comments offered additional suggestions for revisions to the *Guideline* that are addressed in the Response to Comments document located in the docket for this action. In particular, one commenter criticized the multi-stage process recommended by the EPA, which has been applied in the PSD program for more than 25 years. The commenter argued that a cumulative impact analysis must always be conducted and that there was no other rational way to show that a new or modifying source will not cause or contribute to a violation of the NAAQS or PSD increments. In this context, the commenter argued against the use of “significant impact levels” to show, based on a single-source analysis, that an individual source does not cause or contribute to a violation of the NAAQS or PSD increments. The EPA has revised section 9.2.3 of the proposed *Guideline* to make more clear that this two-stage approach is a recommendation and not a requirement. To the extent this recommendation is followed, interested parties retain the opportunity to comment on the adequacy of a single-source analysis and to call for a cumulative impact analysis to make the required demonstration in the context of individual permits.

Further, the EPA is not establishing SILs in this rulemaking and did not intend to codify the use of these values in the *Guideline*. Our use of the term “significant impact” was intended to carry forward principles previously reflected in sections 10.2.1(b), 10.2.1(c) and 10.2.3.2(a) of the 2005 version of the *Guideline*. To make clear that this rule is not codifying the application of

SILs and is only describing the outline of a recommended multi-stage process for making the required demonstration, we have removed the term “significant impact” from many parts of section 9.2.3. In a separate guidance,<sup>20</sup> the EPA has provided a legal and technical rationale that permitting authorities may consider adopting to support the use of “significant impact levels” to quantify a degree of concentration impact below which a source does not have the potential to cause or contribute to a violation. This rationale, which is not adopted by the EPA in this rule, differs in material respects from the basis for a prior EPA rulemaking to adopt SILs that this commenter criticized.

As proposed, we are finalizing revisions to sections 8 and 9 of the *Guideline* to add necessary clarity where requested by public commenters and to correct typographical errors. The EPA fully expects that, by providing more clarity in the *Guideline* of the factors to be considered in conducting both the single-source impact and cumulative impact assessments, permit applicants and permitting authorities will find the proper balance across the various competing factors that contribute to these analyses.

#### 9. Updates on Use of Meteorological Input Data for Regulatory Dispersion Modeling

The EPA solicited comments on the proposed updates regarding use of meteorological input data for regulatory application of dispersion models, including the use of 2-minute Automated Surface Observing Stations (ASOS) for hourly average winds to replace standard hourly observations, and the use of prognostic meteorological data for areas where there is no representative NWS data and it is infeasible or prohibitive to collect site-specific data.

For near-field dispersion modeling applications using NWS ASOS sites, the EPA released a pre-processor to AERMET, called AERMINUTE, in 2011 that calculates hourly averaged winds from 2-minute winds reported every minute at NWS ASOS sites. AERMET substitutes these hourly averaged winds for the standard hourly observations, and thus reduces the number of calms and missing winds for input to AERMOD. The presence of calms and missing winds were due to the METAR reporting methodology of surface observations. In March 2013, the EPA released a memorandum regarding the

use of ASOS data in AERMOD,<sup>53</sup> as well as the use of AERMINUTE. When using meteorological data from ASOS sites for input to AERMOD, hourly averaged winds from AERMINUTE should be used in most cases.

For a near-field dispersion modeling application where there is no representative NWS station, and it is prohibitive or not feasible to collect adequately representative site-specific data, it may be necessary to use prognostic meteorological data for the application. The EPA released the MMIF program that converts the prognostic meteorological data into a format suitable for dispersion modeling applications. The most recent 3 years of prognostic data are preferred. Use of the prognostic data are contingent on the concurrence of the appropriate reviewing authority and collaborating agencies that the data are of acceptable quality and representative of the modeling application.

We received many comments favorable to the use of prognostic meteorological data. While supporting the use of prognostic meteorological data, many commenters also requested additional guidance on running the prognostic meteorological models, assessing the suitability of the model output, and the use of MMIF to generate the meteorological data needed for AERMET and AERMOD. Based on the comments received, the EPA has updated the guidance<sup>54</sup> on use of the prognostic meteorological data.

Therefore, as proposed, the EPA is updating the *Guideline* to recommend that AERMINUTE output should be routinely used in most cases when meteorological data from NWS ASOS sites are used for input to AERMOD and that representative prognostic meteorological data are appropriate for use in dispersion modeling within areas where there is no representative NWS data, or it is infeasible or prohibitive to collect site-specific meteorological data.

#### B. Final Editorial Changes

In this action, the EPA is making editorial changes to update and reorganize information throughout the *Guideline*. These revisions are intended

to make the *Guideline* easier to use, without meaningfully changing the substance of the *Guideline*, by grouping topics together in a more logical manner to make related content easier to find. This in turn should streamline the compliance assessment process.

We describe these editorial changes below for each affected section of the *Guideline*, as well as changes associated with the resolution of the comments and issues discussed in section IV.A. of this preamble and the correction of typographical errors identified in our proposal. For ease of reference, we are publishing the entire text of appendix W and its appendix A, as revised through today's action.

#### 1. Preface

As proposed, the preface is updated to reflect minor text revisions for consistency with the remainder of the *Guideline*.

#### 2. Section 1

The introduction section is updated to reflect the reorganized nature of the revised *Guideline* as proposed. Additional information is provided regarding the importance of CAA section 320 to amendments of the *Guideline*.

#### 3. Section 2

As proposed, section 2 is revised to more appropriately discuss the process by which models are evaluated and considered for use in particular applications. Information from the previous section 9 pertaining to model accuracy and uncertainty is incorporated within this section to clarify how model performance evaluation is critical in determining the suitability of models for particular application.

A discussion is provided in section 2.1 of the three types of models historically used for regulatory demonstrations. For each type of model, some strengths and weaknesses are listed to assist readers in understanding the particular regulatory applications to which they are most appropriate.

In addition, we revised section 2.2 with respect to the recommended practice of progressing from simplified and conservative air quality analysis toward more complex and refined analysis. In this section, we clarify distinctions between various types of models that have previously been described as screening models. In addition, this section clarifies distinctions between models used for screening purposes and screening techniques and demonstration tools that

may be acceptable in certain applications.

A few typographical corrections were made in this section based on public comment and additional review of the proposed regulatory text. Also, based on public comment, clarity was added to the description of the modeling process to indicate that an applicant may choose to implement controls or operational limits based on screening modeling rather than performing additional refined modeling.

#### 4. Section 3

There were minor modifications, including a few typographical corrections, made to section 3 based on public comment to more accurately reflect current EPA practices. As proposed, the discussion of the EPA's MCH is moved to a revised section 3.3 for ease of reference and prominence within the *Guideline*. With this action, EPA Regional Office consultation with and concurrence by the MCH is required on all alternative model approvals. Previously, section 3 included various requirements under a recommendation subheading that were not clearly identified as requirements. Accordingly, we modified section 3 with the incorporation of requirement subsections to eliminate any ambiguity. Finally, the metric used to demonstrate equivalency of models (section 3.2.2) is modified based on public comment to be more appropriate for both deterministic and probabilistic based standards.

#### 5. Section 4

As proposed, section 4 is revised to incorporate the modeling approaches recommended for air quality impact analyses for the following criteria pollutants: CO, lead, SO<sub>2</sub>, NO<sub>2</sub>, and primary PM<sub>2.5</sub> and PM<sub>10</sub>. The revised section 4 is now a combination of the previous sections 4 and 5, reflecting inert criteria pollutants only. We also modified section 4 to incorporate requirement subsections that provide clarity to the various requirements where, previously, sections 4 and 5 included various requirements under recommendation subheadings.

Section 4 now provides an in-depth discussion of screening and refined models, including the introduction of AERSCREEN as the recommended screening model for simple and complex terrain for single sources. We included a clear discussion of each appendix A preferred model in section 4.3. We modified the discussion for each preferred model (*i.e.*, AERMOD Modeling System, CTDMPPLUS, and OCD) from the previous section 4 with

<sup>53</sup> U.S. Environmental Protection Agency, 2013. Use of ASOS Meteorological Data in AERMOD Dispersion Modeling. Memorandum dated March 8, 2013, Office of Air Quality Planning and Standards, Research Triangle Park, NC. [https://www3.epa.gov/ttn/scram/guidance/clarification/20130308\\_Met\\_Data\\_Clarification.pdf](https://www3.epa.gov/ttn/scram/guidance/clarification/20130308_Met_Data_Clarification.pdf).

<sup>54</sup> U.S. Environmental Protection Agency, 2016. Guidance on the Use of the Mesoscale Model Interface Program (MMIF) for AERMOD Applications. Publication No. EPA-454/B-16-003. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

appropriate edits and some streamlining based on information available in the respective model formulation documentation and user's guides.

We added a subsection specifically addressing the modeling recommendations for SO<sub>2</sub> where, previously, section 4 of the *Guideline* was generally understood to be applicable for SO<sub>2</sub>. We made minor updates with respect to the modeling recommendations for each of the other inert criteria pollutants that were previously found in section 5. For NO<sub>2</sub>, the ARM2 is added as a Tier 2 option, and the Tier 3 options of OLM and PVMRM are now regulatory options in AERMOD. For refined modeling of mobile sources, we have revised our previous language regarding the use of the CALINE3 models and are now listing AERMOD, where appropriate. As previously discussed in section IV.A.4 of this preamble, the section on CO modeling has been revised to reference existing guidance for CO screening rather than discussing screening approaches with AERMOD.

Throughout section 4, typographical errors in our proposal were noted by commenters. We have corrected those errors and made some minor revisions for additional clarity addressing some confusion that was expressed in several public comments. Of note, modifications to the requirements discussion of section 4.2 from our proposal were made to account for the potential need for a NAAQS compliance demonstration for long-range transport situations where a near-field assessment for NAAQS is not available or indicates a significant ambient impact at or about 50 km.

#### 6. Section 5

As stated above, much of the previous section 5 (*i.e.*, the portions pertaining to the inert criteria pollutants) is now incorporated into the revised section 4. As proposed, the revised section 5 focuses only on the modeling approaches recommended for ozone and secondary PM<sub>2.5</sub>. Other than addressing a few typographical errors based on public comment, the only additions to section 5 from proposal are a few transitional statements that were added for additional clarity.

Both ozone and secondary PM<sub>2.5</sub> are formed through chemical reactions in the atmosphere and are not appropriately modeled with traditional steady-state Gaussian plume models, such as AERMOD. Chemical transport models are necessary to appropriately assess the single-source air quality impacts of precursor pollutants on the formation of ozone or secondary PM<sub>2.5</sub>.

While the revisions to section 5 do not specify a particular EPA-preferred model or technique for use in air quality assessments, we have established a two-tiered screening approach for ozone and secondary PM<sub>2.5</sub> with appropriate references to the EPA's new single-source modeling guidance. The first tier consists of technically credible and appropriate relationships between emissions and the impacts developed from existing modeling simulations. If existing technical information is not available or appropriate, then a second tier approach would apply, involving use of sophisticated CTMs (*e.g.*, photochemical grid models) as determined in consultation with the appropriate EPA Regional Office on a case-by-case basis based upon the EPA's new single-source modeling guidance.

#### 7. Section 6

As proposed, section 6 is revised to more clearly address the modeling recommendations of other federal agencies, such as the FLMs, that have been developed in response to EPA rules or standards. Based on public comment from a tribal association and several tribes, we have added clarifying language that indicates that other state, local, or tribal agencies with air quality and land management responsibilities may also have specific modeling approaches for their own regulatory or other requirements. While no attempt was made to comprehensively discuss each topic, we provide appropriate references to the respective federal agency guidance documents.

The revisions to section 6 focus primarily on AQRVs, including near-field and long-range transport assessments for visibility impairment and deposition. The interests of the Bureau of Ocean Energy and Management (BOEM) for Outer Continental Shelf (OCS) permitting situations and the FAA for airport and air base permitting situations are represented in section 6.3.

The discussion of Good Engineering Practices (GEP) for stack height consideration is modified and moved to section 7. We have removed the discussion of long-range transport for PSD Class I increments and the references to the previously preferred long-range transport model, CALPUFF, in accordance with the more detailed discussion in section IV.A.6 of this preamble.

#### 8. Section 7

As proposed, we revised section 7 to be more streamlined and appropriate to the variety of general modeling issues and considerations that are not covered

in sections 4, 5, and 6 of the *Guideline*. Information concerning design concentrations and receptor sites is moved to section 9. The discussion of stability categories has been removed from section 7 because it is specifically addressed in the model formulation documentation and guidance for the dispersion models that require stability categories to be defined. As stated above, the GEP discussion from the previous section 6 is now incorporated into this section. Based on public comment, we added a statement to the plume rise discussion to clarify that refinements to the preferred model may be considered for plume rise and downwash effects only with agreement from the appropriate reviewing authority and approval by the EPA Regional Office.

We expanded the recommendations for determining rural or urban dispersion coefficients to provide more clarity with respect to appropriate characterization within AERMOD, including a discussion on the existence of highly industrialized areas where population density is low, which may be best treated with urban rather than rural dispersion coefficients. References to CALPUFF in the Complex Winds subsection have been removed in keeping with our approach to not explicitly name models that are not listed in appendix A, so as to not imply any preferential status vis-a-vis other available models. If necessary for special complex wind situations, the setup and application of an alternative model should now be determined in consultation with the appropriate reviewing authority. Finally, we revised section 7, as proposed, to include a new discussion of modeling considerations specific to mobile sources.

#### 9. Section 8

We made extensive updates and modifications to section 8, as proposed, to reflect current EPA practices, requirements, and recommendations for determining the appropriate modeling domain and model input data from new or modifying source(s) or sources under consideration for a revised permit limit, from background concentrations (including air quality monitoring data and nearby and others sources), and from meteorology. As with earlier sections, we modified section 8 to incorporate requirement subsections where previously section 8 ambiguously included various requirements under recommendation subheadings.

Commenters identified typographical errors that have been corrected along with appropriate clarifications in this section.

The Background Concentration subsection has been significantly modified from the existing *Guideline* to include a clearer and more comprehensive discussion of “nearby” and “other” sources. This is intended to eliminate confusion over how to identify nearby sources that should be explicitly modeled and all other sources that should be generally represented by air quality monitoring data. In addition, a brief discussion on the use of photochemical grid modeling to appropriately characterize background concentrations has been included in this section. Updates to Tables 8–1 and 8–2 are made per changes in the considerations for nearby sources, as discussed in section IV.A.8 of this preamble. Based on several public comments, Table 8–2 was further updated to correctly state that the operational level for nearby sources for short-term average times is the “temporally representative level when actually operating, reflective of the most recent 2 years.”

The use of prognostic mesoscale meteorological models to provide meteorological input for regulatory dispersion modeling applications has been incorporated throughout the “Meteorological Input Data” subsection, including the introduction of the MMIF as a tool to inform regulatory model applications. We made additional minor modifications to the recommendations in this subsection based on current EPA practices, of which the most substantive edit was the recommendation to use the AERMINUTE meteorological data processor to calculate hourly average wind speed and direction when processing NWS ASOS data for developing AERMET meteorological inputs to the AERMOD dispersion model.

#### 10. Section 9

As proposed, we moved all of the information previously in section 9 related to model accuracy and evaluation into other sections in the revised *Guideline* (primarily to the revised section 2 and some to the revised section 4). This provides greater clarity in those topics as applied to selection of models under the *Guideline*. We removed a subsection on the “Use of Uncertainty in Decision Making.” Also, we revised section 9 to focus on the regulatory application of models, which includes the majority of the information found previously in section 10.

We revised the discussion portion of section 9 to more clearly summarize the general concepts presented in earlier sections of the *Guideline* and to set the

stage for the appropriate regulatory application of models and/or, in rare circumstances, air quality monitoring data in lieu of modeling. The importance of developing and vetting a modeling protocol is more prominently presented in a separate subsection.

The information related to design concentrations is updated and unified from previous language found in sections 7 and 10. An expanded discussion of receptor sites is based on language from the previous section 7 and new considerations given past practices of model users tending to define an excessively large and inappropriate number of receptors based on vague guidance.

We added the recommendations for NAAQS and PSD increments compliance demonstrations that had been in section 10. In additions, we updated the recommendations to more clearly and accurately reflect the long-standing practice of performing a single-source impact analysis as a first stage of the NAAQS and PSD increments compliance demonstration and, as necessary, conducting a more comprehensive cumulative impact analysis as the second stage. The appropriate considerations and applications of screening and/or refined model are described in each stage.

Finally, we revised the “Use of Measured Data in Lieu of Model Estimates” subsection to provide more details on the process for determining the rare circumstances in which air quality monitoring data may be considered for determining the most appropriate emissions limit for a modification to an existing source. As with other portions of the revised section 9, the language throughout this subsection is updated to reflect current EPA practices, as appropriate.

#### 11. Section 10

As proposed, we incorporated the majority of the information found previously in section 10 into the revised section 9. Section 10 now consists of the references that were in the previous section 12. Each reference is updated, as appropriate, based on the text revisions throughout the *Guideline*.

#### 12. Section 11

In a streamlining effort, we removed the bibliography section from the *Guideline* as proposed.

#### 13. Section 12

As stated earlier, this references section is now section 10 with appropriate updates.

#### 14. Appendix A to the *Guideline*

As proposed, we revised appendix A to the *Guideline* to remove the BLP model, CALINE3, and CALPUFF as refined air quality models preferred for specific regulatory applications. The rationale for the removal of these air quality models from the preferred status can be found in section IV.A.2, section IV.A.4, and section IV.A.6 of this preamble. Finally, we made minor modifications, including a few typographical corrections, to appendix A based on public comment and additional review of the proposed regulatory text.

### V. Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. The OMB determined that this regulatory action could potentially interfere with an action taken or planned by another agency. Any changes made in response to OMB recommendations have been documented in the docket.

#### B. Paperwork Reduction Act (PRA)

This final action does not impose an information collection burden under the PRA. This action does not contain any information collection activities, nor does it add any information collection requirements beyond those imposed by existing NSR requirements.

#### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule.

The modeling techniques described in this action are primarily used by air agencies and by industries owning major sources subject to NSR permitting requirements. To the extent that any small entities would have to conduct air quality assessments, using the models and/or techniques described in this action are not expected to pose any additional burden on these entities. The

revisions to the existing EPA-preferred model, AERMOD, serve to increase efficiency and accuracy by changing only mathematical formulations and specific data elements. Also, this action will streamline resources necessary to conduct modeling with AERMOD by incorporating model algorithms from the BLP model. Although this final action calls for new models and/or techniques for use in addressing ozone and secondary PM<sub>2.5</sub>, we expect most small entities will generally be able to rely on existing modeling simulations. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

#### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments or the private sector beyond those imposed by the existing NSR requirements.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. The final rule provides revisions to the *Guideline* which is used by the EPA, other federal, state, territorial, local, and tribal air quality agencies, and industry to prepare and review new source permits, source permit modifications, SIP submittals and revisions, conformity, and other air quality assessments required under EPA regulation. The Tribal Air Rule implements the provisions of section 301(d) of the CAA authorizing eligible tribes to implement their own tribal air program. Thus, Executive Order 13175 does not apply to this action. In the spirit of Executive Order 13175, the EPA provided an informational webinar with the National Tribal Air Association (NTAA) on September 10, 2015, and also received comment on the proposed action from the NTAA and several individual tribes. These comments and

our responses are included in the docket for this action.

#### *G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we have concluded that this action is not likely to have any adverse energy effects because its purpose is to streamline the procedures by which stakeholders apply air quality modeling and technique in conducting their air quality assessments required under the CAA and, also, increases the scientific credibility and accuracy of the models and techniques used for conducting these assessments.

#### *I. National Technology Transfer and Advancement Act*

This rulemaking does not involve technical standards.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action provides updates and clarifications to the *Guideline* and does not have any impact on human health or the environment.

#### *K. Congressional Review Act (CRA)*

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

#### **List of Subjects in 40 CFR Part 51**

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: December 20, 2016.

**Gina McCarthy**,  
Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency is amending title 40, chapter I of the Code of Federal Regulations as follows:

#### **PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS**

■ 1. The authority citation for part 51 continues to read as follows:

**Authority:** 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 2. Appendix W to part 51 is revised to read as follows:

#### **Appendix W to Part 51—Guideline on Air Quality Models**

##### **Preface**

a. Industry and control agencies have long expressed a need for consistency in the application of air quality models for regulatory purposes. In the 1977 Clean Air Act (CAA), Congress mandated such consistency and encouraged the standardization of model applications. The *Guideline on Air Quality Models* (hereafter, *Guideline*) was first published in April 1978 to satisfy these requirements by specifying models and providing guidance for their use. The *Guideline* provides a common basis for estimating the air quality concentrations of criteria pollutants used in assessing control strategies and developing emissions limits.

b. The continuing development of new air quality models in response to regulatory requirements and the expanded requirements for models to cover even more complex problems have emphasized the need for periodic review and update of guidance on these techniques. Historically, three primary activities have provided direct input to revisions of the *Guideline*. The first is a series of periodic EPA workshops and modeling conferences conducted for the purpose of ensuring consistency and providing clarification in the application of models. The second activity was the solicitation and review of new models from the technical and user community. In the March 27, 1980, **Federal Register**, a procedure was outlined for the submittal to the EPA of privately developed models. After extensive evaluation and scientific review, these models, as well as those made available by the EPA, have been considered for recognition in the *Guideline*. The third activity is the extensive on-going research efforts by the EPA and

others in air quality and meteorological modeling.

c. Based primarily on these three activities, new sections and topics have been included as needed. The EPA does not make changes to the guidance on a predetermined schedule, but rather on an as-needed basis. The EPA believes that revisions of the *Guideline* should be timely and responsive to user needs and should involve public participation to the greatest possible extent. All future changes to the guidance will be proposed and finalized in the **Federal Register**. Information on the current status of modeling guidance can always be obtained from the EPA's Regional Offices.

## Table of Contents

### List of Tables

- 1.0 Introduction
- 2.0 Overview of Model Use
- 2.1 Suitability of Models
  - 2.1.1 Model Accuracy and Uncertainty
- 2.2 Levels of Sophistication of Air Quality Analyses and Models
- 2.3 Availability of Models
- 3.0 Preferred and Alternative Air Quality Models
- 3.1 Preferred Models
  - 3.1.1 Discussion
  - 3.1.2 Requirements
- 3.2 Alternative Models
  - 3.2.1 Discussion
  - 3.2.2 Requirements
- 3.3 EPA's Model Clearinghouse
- 4.0 Models for Carbon Monoxide, Lead, Sulfur Dioxide, Nitrogen Dioxide and Primary Particulate Matter
- 4.1 Discussion
- 4.2 Requirements
  - 4.2.1 Screening Models and Techniques
    - 4.2.1.1 AERSCREEN
    - 4.2.1.2 CTSCREEN
    - 4.2.1.3 Screening in Complex Terrain
  - 4.2.2 Refined Models
    - 4.2.2.1 AERMOD
    - 4.2.2.2 CTDMPPLUS
    - 4.2.2.3 OCD
  - 4.2.3 Pollutant Specific Modeling Requirements
    - 4.2.3.1 Models for Carbon Monoxide
    - 4.2.3.2 Models for Lead
    - 4.2.3.3 Models for Sulfur Dioxide
    - 4.2.3.4 Models for Nitrogen Dioxide
    - 4.2.3.5 Models for PM<sub>2.5</sub>
    - 4.2.3.6 Models for PM<sub>10</sub>
- 5.0 Models for Ozone and Secondarily Formed Particulate Matter
- 5.1 Discussion
- 5.2 Recommendations
- 5.3 Recommended Models and Approaches for Ozone
  - 5.3.1 Models for NAAQS Attainment Demonstrations and Multi-Source Air Quality Assessments
  - 5.3.2 Models for Single-Source Air Quality Assessments
- 5.4 Recommended Models and Approaches for Secondarily Formed PM<sub>2.5</sub>
  - 5.4.1 Models for NAAQS Attainment Demonstrations and Multi-Source Air Quality Assessments
  - 5.4.2 Models for Single-Source Air Quality Assessments
- 6.0 Modeling for Air Quality Related Values and Other Governmental Programs

- 6.1 Discussion
- 6.2 Air Quality Related Values
  - 6.2.1 Visibility
    - 6.2.1.1 Models for Estimating Near-Field Visibility Impairment
    - 6.2.1.2 Models for Estimating Visibility Impairment for Long-Range Transport
  - 6.2.2 Models for Estimating Deposition Impacts
- 6.3 Modeling Guidance for Other Governmental Programs
- 7.0 General Modeling Considerations
- 7.1 Discussion
- 7.2 Recommendations
  - 7.2.1 All sources
    - 7.2.1.1 Dispersion Coefficients
    - 7.2.1.2 Complex Winds
    - 7.2.1.3 Gravitational Settling and Deposition
  - 7.2.2 Stationary Sources
    - 7.2.2.1 Good Engineering Practice Stack Height
    - 7.2.2.2 Plume Rise
  - 7.2.3 Mobile Sources
- 8.0 Model Input Data
- 8.1 Modeling Domain
  - 8.1.1 Discussion
  - 8.1.2 Requirements
- 8.2 Source Data
  - 8.2.1 Discussion
  - 8.2.2 Requirements
- 8.3 Background Concentrations
  - 8.3.1 Discussion
  - 8.3.2 Recommendations for Isolated Single Sources
  - 8.3.3 Recommendations for Multi-Source Areas
- 8.4 Meteorological Input Data
  - 8.4.1 Discussion
  - 8.4.2 Recommendations and Requirements
    - 8.4.3 National Weather Service Data
      - 8.4.3.1 Discussion
      - 8.4.3.2 Recommendations
    - 8.4.4 Site-specific data
      - 8.4.4.1 Discussion
      - 8.4.4.2 Recommendations
  - 8.4.5 Prognostic meteorological data
    - 8.4.5.1 Discussion
    - 8.4.5.2 Recommendations
  - 8.4.6 Treatment of Near-Calms and Calms
    - 8.4.6.1 Discussion
    - 8.4.6.2 Recommendations
- 9.0 Regulatory Application of Models
- 9.1 Discussion
- 9.2 Recommendations
  - 9.2.1 Modeling Protocol
  - 9.2.2 Design Concentration and Receptor Sites
  - 9.2.3 NAAQS and PSD Increments Compliance Demonstrations for New or Modified Sources
    - 9.2.3.1 Considerations in Developing Emissions Limits
  - 9.2.4 Use of Measured Data in Lieu of Model Estimates

### 10.0 References

Appendix A to Appendix W of Part 51—Summaries of Preferred Air Quality Models

### List of Tables

Table No.	Title
8-1 .....	Point Source Model Emission Inputs for SIP Revisions of Inert Pollutants.

Table No.	Title
8-2 .....	Point Source Model Emission Inputs for NAAQS Compliance in PSD Demonstrations.

### 1.0 Introduction

a. The *Guideline* provides air quality modeling techniques that should be applied to State Implementation Plan (SIP) submittals and revisions, to New Source Review (NSR), including new or modifying sources under Prevention of Significant Deterioration (PSD),<sup>1,2,3</sup> conformity analyses,<sup>4</sup> and other air quality assessments required under EPA regulation. Applicable only to criteria air pollutants, the *Guideline* is intended for use by the EPA Regional Offices in judging the adequacy of modeling analyses performed by the EPA, by state, local, and tribal permitting authorities, and by industry. It is appropriate for use by other federal government agencies and by state, local, and tribal agencies with air quality and land management responsibilities. The *Guideline* serves to identify, for all interested parties, those modeling techniques and databases that the EPA considers acceptable. The *Guideline* is not intended to be a compendium of modeling techniques. Rather, it should serve as a common measure of acceptable technical analysis when supported by sound scientific judgment.

b. Air quality measurements<sup>5</sup> are routinely used to characterize ambient concentrations of criteria pollutants throughout the nation but are rarely sufficient for characterizing the ambient impacts of individual sources or demonstrating adequacy of emissions limits for an existing source due to limitations in spatial and temporal coverage of ambient monitoring networks. The impacts of new sources that do not yet exist, and modifications to existing sources that have yet to be implemented, can only be determined through modeling. Thus, models have become a primary analytical tool in most air quality assessments. Air quality measurements can be used in a complementary manner to air quality models, with due regard for the strengths and weaknesses of both analysis techniques, and are particularly useful in assessing the accuracy of model estimates.

c. It would be advantageous to categorize the various regulatory programs and to apply a designated model to each proposed source needing analysis under a given program. However, the diversity of the nation's topography and climate, and variations in source configurations and operating characteristics dictate against a strict modeling "cookbook." There is no one model capable of properly addressing all conceivable situations even within a broad category such as point sources. Meteorological phenomena associated with threats to air quality standards are rarely amenable to a single mathematical treatment; thus, case-by-case analysis and judgment are frequently required. As modeling efforts become more complex, it is increasingly important that they be directed by highly competent individuals with a broad range of experience and knowledge in air quality



meteorology. Further, they should be coordinated closely with specialists in emissions characteristics, air monitoring and data processing. The judgment of experienced meteorologists, atmospheric scientists, and analysts is essential.

d. The model that most accurately estimates concentrations in the area of interest is always sought. However, it is clear from the needs expressed by the EPA Regional Offices, by state, local, and tribal agencies, by many industries and trade associations, and also by the deliberations of Congress, that consistency in the selection and application of models and databases should also be sought, even in case-by-case analyses. Consistency ensures that air quality control agencies and the general public have a common basis for estimating pollutant concentrations, assessing control strategies, and specifying emissions limits. Such consistency is not, however, promoted at the expense of model and database accuracy. The *Guideline* provides a consistent basis for selection of the most accurate models and databases for use in air quality assessments.

e. Recommendations are made in the *Guideline* concerning air quality models and techniques, model evaluation procedures, and model input databases and related requirements. The guidance provided here should be followed in air quality analyses relative to SIPs, NSR, and in supporting analyses required by the EPA and by state, local, and tribal permitting authorities. Specific models are identified for particular applications. The EPA may approve the use of an alternative model or technique that can be demonstrated to be more appropriate than those recommended in the *Guideline*. In all cases, the model or technique applied to a given situation should be the one that provides the most accurate representation of atmospheric transport, dispersion, and chemical transformations in the area of interest. However, to ensure consistency, deviations from the *Guideline* should be carefully documented as part of the public record and fully supported by the appropriate reviewing authority, as discussed later.

f. From time to time, situations arise requiring clarification of the intent of the guidance on a specific topic. Periodic workshops are held with EPA headquarters, EPA Regional Offices, and state, local, and tribal agency modeling representatives to ensure consistency in modeling guidance and to promote the use of more accurate air quality models, techniques, and databases. The workshops serve to provide further explanations of *Guideline* requirements to the EPA Regional Offices and workshop materials are issued with this clarifying information. In addition, findings from ongoing research programs, new model development, or results from model evaluations and applications are continuously evaluated. Based on this information, changes in the applicable guidance may be indicated and appropriate revisions to the *Guideline* may be considered.

g. All changes to the *Guideline* must follow rulemaking requirements since the *Guideline* is codified in appendix W to 40 Code of Federal Regulations (CFR) part 51. The EPA

will promulgate proposed and final rules in the **Federal Register** to amend this appendix. The EPA utilizes the existing procedures under CAA section 320 that requires the EPA to conduct a Conference on Air Quality Modeling at least every 3 years (CAA 320, 42 U.S.C. 7620). These modeling conferences are intended to develop standardized air quality modeling procedures and form the basis for associated revisions to this *Guideline* in support of the EPA's continuing effort to prescribe with "reasonable particularity" air quality models and meteorological and emission databases suitable for modeling National Ambient Air Quality Standards (NAAQS)<sup>6</sup> and PSD increments. Ample opportunity for public comment will be provided for each proposed change and public hearings scheduled.

h. A wide range of topics on modeling and databases are discussed in the *Guideline*. Section 2 gives an overview of models and their suitability for use in regulatory applications. Section 3 provides specific guidance on the determination of preferred air quality models and on the selection of alternative models or techniques. Sections 4 through 6 provide recommendations on modeling techniques for assessing criteria pollutant impacts from single and multiple sources with specific modeling requirements for selected regulatory applications. Section 7 discusses general considerations common to many modeling analyses for stationary and mobile sources. Section 8 makes recommendations for data inputs to models including source, background air quality, and meteorological data. Section 9 summarizes how estimates and measurements of air quality are used in assessing source impact and in evaluating control strategies.

i. Appendix W to 40 CFR part 51 contains an appendix: Appendix A. Thus, when reference is made to "appendix A" in this document, it refers to appendix A to appendix W to 40 CFR part 51. Appendix A contains summaries of refined air quality models that are "preferred" for particular applications; both EPA models and models developed by others are included.

## 2.0 Overview of Model Use

a. Increasing reliance has been placed on concentration estimates from air quality models as the primary basis for regulatory decisions concerning source permits and emission control requirements. In many situations, such as review of a proposed new source, no practical alternative exists. Before attempting to implement the guidance contained in this document, the reader should be aware of certain general information concerning air quality models and their evaluation and use. Such information is provided in this section.

### 2.1 Suitability of Models

a. The extent to which a specific air quality model is suitable for the assessment of source impacts depends upon several factors. These include: (1) The topographic and meteorological complexities of the area; (2) the detail and accuracy of the input databases, *i.e.*, emissions inventory, meteorological data, and air quality data; (3) the manner in which complexities of

atmospheric processes are handled in the model; (4) the technical competence of those undertaking such simulation modeling; and (5) the resources available to apply the model. Any of these factors can have a significant influence on the overall model performance, which must be thoroughly evaluated to determine the suitability of an air quality model to a particular application or range of applications.

b. Air quality models are most accurate and reliable in areas that have gradual transitions of land use and topography. Meteorological conditions in these areas are spatially uniform such that observations are broadly representative and air quality model projections are not further complicated by a heterogeneous environment. Areas subject to major topographic influences experience meteorological complexities that are often difficult to measure and simulate. Models with adequate performance are available for increasingly complex environments. However, they are resource intensive and frequently require site-specific observations and formulations. Such complexities and the related challenges for the air quality simulation should be considered when selecting the most appropriate air quality model for an application.

c. Appropriate model input data should be available before an attempt is made to evaluate or apply an air quality model. Assuming the data are adequate, the greater the detail with which a model considers the spatial and temporal variations in meteorological conditions and permit-enforceable emissions, the greater the ability to evaluate the source impact and to distinguish the effects of various control strategies.

d. There are three types of models that have historically been used in the regulatory demonstrations applicable in the *Guideline*, each having strengths and weaknesses that lend themselves to particular regulatory applications.

i. Gaussian plume models use a "steady-state" approximation, which assumes that over the model time step, the emissions, meteorology and other model inputs, are constant throughout the model domain, resulting in a resolved plume with the emissions distributed throughout the plume according to a Gaussian distribution. This formulation allows Gaussian models to estimate near-field impacts of a limited number of sources at a relatively high resolution, with temporal scales of an hour and spatial scales of meters. However, this formulation allows for only relatively inert pollutants, with very limited considerations of transformation and removal (*e.g.*, deposition), and further limits the domain for which the model may be used. Thus, Gaussian models may not be appropriate if model inputs are changing sharply over the model time step or within the desired model domain, or if more advanced considerations of chemistry are needed.

ii. Lagrangian puff models, on the other hand, are non-steady-state, and assume that model input conditions are changing over the model domain and model time step. Lagrangian models can also be used to determine near- and far-field impacts from a

limited number of sources. Traditionally, Lagrangian models have been used for relatively inert pollutants, with slightly more complex considerations of removal than Gaussian models. Some Lagrangian models treat in-plume gas and particulate chemistry. However, these models require time and space varying concentration fields of oxidants and, in the case of fine particulate matter (PM<sub>2.5</sub>), neutralizing agents, such as ammonia. Reliable background fields are critical for applications involving secondary pollutant formation because secondary impacts generally occur when in-plume precursors mix and react with species in the background atmosphere.<sup>7,8</sup> These oxidant and neutralizing agents are not routinely measured, but can be generated with a three-dimensional photochemical grid model.

iii. Photochemical grid models are three-dimensional Eulerian grid-based models that treat chemical and physical processes in each grid cell and use diffusion and transport processes to move chemical species between grid cells.<sup>9</sup> Eulerian models assume that emissions are spread evenly throughout each model grid cell. At coarse grid resolutions, Eulerian models have difficulty with fine scale resolution of individual plumes. However, these types of models can be appropriately applied for assessment of near-field and regional scale reactive pollutant impacts from specific sources<sup>7,10,11,12</sup> or all sources.<sup>13,14,15</sup> Photochemical grid models simulate a more realistic environment for chemical transformation,<sup>7,12</sup> but simulations can be more resource intensive than Lagrangian or Gaussian plume models.

e. Competent and experienced meteorologists, atmospheric scientists, and analysts are an essential prerequisite to the successful application of air quality models. The need for such specialists is critical when sophisticated models are used or the area has complicated meteorological or topographic features. It is important to note that a model applied improperly or with inappropriate data can lead to serious misjudgments regarding the source impact or the effectiveness of a control strategy.

f. The resource demands generated by use of air quality models vary widely depending on the specific application. The resources required may be important factors in the selection and use of a model or technique for a specific analysis. These resources depend on the nature of the model and its complexity, the detail of the databases, the difficulty of the application, the amount and level of expertise required, and the costs of manpower and computational facilities.

#### 2.1.1 Model Accuracy and Uncertainty

a. The formulation and application of air quality models are accompanied by several sources of uncertainty. "Irreducible" uncertainty stems from the "unknown" conditions, which may not be explicitly accounted for in the model (e.g., the turbulent velocity field). Thus, there are likely to be deviations from the observed concentrations in individual events due to variations in the unknown conditions. "Reducible" uncertainties<sup>16</sup> are caused by: (1) Uncertainties in the "known" input conditions (e.g., emission characteristics and meteorological data); (2) errors in the

measured concentrations; and (3) inadequate model physics and formulation.

b. Evaluations of model accuracy should focus on the reducible uncertainty associated with physics and the formulation of the model. The accuracy of the model is normally determined by an evaluation procedure which involves the comparison of model concentration estimates with measured air quality data.<sup>17</sup> The statement of model accuracy is based on statistical tests or performance measures such as bias, error, correlation, etc.<sup>18,19</sup>

c. Since the 1980's, the EPA has worked with the modeling community to encourage development of standardized model evaluation methods and the development of continually improved methods for the characterization of model performance.<sup>16,18,20,21,22</sup> There is general consensus on what should be considered in the evaluation of air quality models; namely, quality assurance planning, documentation and scrutiny should be consistent with the intended use and should include:

- Scientific peer review;
- Supportive analyses (diagnostic evaluations, code verification, sensitivity analyses);
- Diagnostic and performance evaluations with data obtained in trial locations; and
- Statistical performance evaluations in the circumstances of the intended applications.

Performance evaluations and diagnostic evaluations assess different qualities of how well a model is performing, and both are needed to establish credibility within the client and scientific community.

d. Performance evaluations allow the EPA and model users to determine the relative performance of a model in comparison with alternative modeling systems. Diagnostic evaluations allow determination of a model capability to simulate individual processes that affect the results, and usually employ smaller spatial/temporal scale data sets (e.g., field studies). Diagnostic evaluations enable the EPA and model users to build confidence that model predictions are accurate for the right reasons. However, the objective comparison of modeled concentrations with observed field data provides only a partial means for assessing model performance. Due to the limited supply of evaluation datasets, there are practical limits in assessing model performance. For this reason, the conclusions reached in the science peer reviews and the supportive analyses have particular relevance in deciding whether a model will be useful for its intended purposes.

#### 2.2 Levels of Sophistication of Air Quality Analyses and Models

a. It is desirable to begin an air quality analysis by using simplified and conservative methods followed, as appropriate, by more complex and refined methods. The purpose of this approach is to streamline the process and sufficiently address regulatory requirements by eliminating the need of more detailed modeling when it is not necessary in a specific regulatory application. For example, in the context of a PSD permit application, a simplified and conservative analysis may be sufficient where it shows the

proposed construction clearly will not cause or contribute to ambient concentrations in excess of either the NAAQS or the PSD increments.<sup>2,3</sup>

b. There are two general levels of sophistication of air quality models. The first level consists of screening models that provide conservative modeled estimates of the air quality impact of a specific source or source category based on simplified assumptions of the model inputs (e.g., preset, worst-case meteorological conditions). In the case of a PSD assessment, if a screening model indicates that the increase in concentration attributable to the source could cause or contribute to a violation of any NAAQS or PSD increment, then the second level of more sophisticated models should be applied unless appropriate controls or operational restrictions are implemented based on the screening modeling.

c. The second level consists of refined models that provide more detailed treatment of physical and chemical atmospheric processes, require more detailed and precise input data, and provide spatially and temporally resolved concentration estimates. As a result, they provide a more sophisticated and, at least theoretically, a more accurate estimate of source impact and the effectiveness of control strategies.

d. There are situations where a screening model or a refined model is not available such that screening and refined modeling are not viable options to determine source-specific air quality impacts. In such situations, a screening technique or reduced-form model may be viable options for estimating source impacts.

i. Screening techniques are differentiated from a screening model in that screening techniques are approaches that make simplified and conservative assumptions about the physical and chemical atmospheric processes important to determining source impacts, while screening models make assumptions about conservative inputs to a specific model. The complexity of screening techniques ranges from simplified assumptions of chemistry applied to refined or screening model output to sophisticated approximations of the chemistry applied within a refined model.

ii. Reduced-form models are computationally efficient simulation tools for characterizing the pollutant response to specific types of emission reductions for a particular geographic area or background environmental conditions that reflect underlying atmospheric science of a refined model but reduce the computational resources of running a complex, numerical air quality model such as a photochemical grid model.

In such situations, an attempt should be made to acquire or improve the necessary databases and to develop appropriate analytical techniques, but the screening technique or reduced-form model may be sufficient in conducting regulatory modeling applications when applied in consultation with the EPA Regional Office.

e. Consistent with the general principle described in paragraph 2.2(a), the EPA may establish a demonstration tool or method as a sufficient means for a user or applicant to

make a demonstration required by regulation, either by itself or as part of a modeling demonstration. To be used for such regulatory purposes, such a tool or method must be reflected in a codified regulation or have a well-documented technical basis and reasoning that is contained or incorporated in the record of the regulatory decision in which it is applied.

### 2.3 Availability of Models

a. For most of the screening and refined models discussed in the *Guideline*, codes, associated documentation and other useful information are publicly available for download from the EPA's Support Center for Regulatory Atmospheric Modeling (SCRAM) Web site at <https://www.epa.gov/scram>. This is a Web site with which air quality modelers should become familiar and regularly visit for important model updates and additional clarifications and revisions to modeling guidance documents that are applicable to EPA programs and regulations. Codes and documentation may also be available from the National Technical Information Service (NTIS), <http://www.ntis.gov>, and, when available, is referenced with the appropriate NTIS accession number.

### 3.0 Preferred and Alternative Air Quality Models

a. This section specifies the approach to be taken in determining preferred models for use in regulatory air quality programs. The status of models developed by the EPA, as well as those submitted to the EPA for review and possible inclusion in this *Guideline*, is discussed in this section. The section also provides the criteria and process for obtaining EPA approval for use of alternative models for individual cases in situations where the preferred models are not applicable or available. Additional sources of relevant modeling information are: the EPA's Model Clearinghouse<sup>23</sup> (section 3.3); EPA modeling conferences; periodic Regional, State, and Local Modelers' Workshops; and the EPA's SCRAM Web site (section 2.3).

b. When approval is required for a specific modeling technique or analytical procedure in this *Guideline*, we refer to the "appropriate reviewing authority." Many states and some local agencies administer NSR permitting under programs approved into SIPs. In some EPA regions, federal authority to administer NSR permitting and related activities has been delegated to state or local agencies. In these cases, such agencies "stand in the shoes" of the respective EPA Region. Therefore, depending on the circumstances, the appropriate reviewing authority may be an EPA Regional Office, a state, local, or tribal agency, or perhaps the Federal Land Manager (FLM). In some cases, the *Guideline* requires review and approval of the use of an alternative model by the EPA Regional Office (sometimes stated as "Regional Administrator"). For all approvals of alternative models or techniques, the EPA Regional Office will coordinate and shall seek concurrence with the EPA's Model Clearinghouse. If there is any question as to the appropriate reviewing authority, you should contact the EPA Regional Office

modeling contact ([https://www3.epa.gov/ttn/scram/guidance\\_cont\\_regions.htm](https://www3.epa.gov/ttn/scram/guidance_cont_regions.htm)), whose jurisdiction generally includes the physical location of the source in question and its expected impacts.

c. In all regulatory analyses, early discussions among the EPA Regional Office staff, state, local, and tribal agency staff, industry representatives, and where appropriate, the FLM, are invaluable and are strongly encouraged. Prior to the actual analyses, agreement on the databases to be used, modeling techniques to be applied, and the overall technical approach helps avoid misunderstandings concerning the final results and may reduce the later need for additional analyses. The preparation of a written modeling protocol that is vetted with the appropriate reviewing authority helps to keep misunderstandings and resource expenditures at a minimum.

d. The identification of preferred models in this *Guideline* should not be construed as a determination that the preferred models identified here are to be permanently used to the exclusion of all others or that they are the only models available for relating emissions to air quality. The model that most accurately estimates concentrations in the area of interest is always sought. However, designation of specific preferred models is needed to promote consistency in model selection and application.

#### 3.1 Preferred Models

##### 3.1.1 Discussion

a. The EPA has developed some models suitable for regulatory application, while other models have been submitted by private developers for possible inclusion in the *Guideline*. Refined models that are preferred and required by the EPA for particular applications have undergone the necessary peer scientific reviews<sup>24,25</sup> and model performance evaluation exercises<sup>26,27</sup> that include statistical measures of model performance in comparison with measured air quality data as described in section 2.1.1.

b. An American Society for Testing and Materials (ASTM) reference<sup>28</sup> provides a general philosophy for developing and implementing advanced statistical evaluations of atmospheric dispersion models, and provides an example statistical technique to illustrate the application of this philosophy. Consistent with this approach, the EPA has determined and applied a specific evaluation protocol that provides a statistical technique for evaluating model performance for predicting peak concentration values, as might be observed at individual monitoring locations.<sup>29</sup>

c. When a single model is found to perform better than others, it is recommended for application as a preferred model and listed in appendix A. If no one model is found to clearly perform better through the evaluation exercise, then the preferred model listed in appendix A may be selected on the basis of other factors such as past use, public familiarity, resource requirements, and availability. Accordingly, the models listed in appendix A meet these conditions:

i. The model must be written in a common programming language, and the executable(s) must run on a common computer platform.

ii. The model must be documented in a user's guide or model formulation report which identifies the mathematics of the model, data requirements and program operating characteristics at a level of detail comparable to that available for other recommended models in appendix A.

iii. The model must be accompanied by a complete test dataset including input parameters and output results. The test data must be packaged with the model in computer-readable form.

iv. The model must be useful to typical users, e.g., state air agencies, for specific air quality control problems. Such users should be able to operate the computer program(s) from available documentation.

v. The model documentation must include a robust comparison with air quality data (and/or tracer measurements) or with other well-established analytical techniques.

vi. The developer must be willing to make the model and source code available to users at reasonable cost or make them available for public access through the Internet or National Technical Information Service. The model and its code cannot be proprietary.

d. The EPA's process of establishing a preferred model includes a determination of technical merit, in accordance with the above six items, including the practicality of the model for use in ongoing regulatory programs. Each model will also be subjected to a performance evaluation for an appropriate database and to a peer scientific review. Models for wide use (not just an isolated case) that are found to perform better will be proposed for inclusion as preferred models in future *Guideline* revisions.

e. No further evaluation of a preferred model is required for a particular application if the EPA requirements for regulatory use specified for the model in the *Guideline* are followed. Alternative models to those listed in appendix A should generally be compared with measured air quality data when they are used for regulatory applications consistent with recommendations in section 3.2.

##### 3.1.2 Requirements

a. Appendix A identifies refined models that are preferred for use in regulatory applications. If a model is required for a particular application, the user must select a model from appendix A or follow procedures in section 3.2.2 for use of an alternative model or technique. Preferred models may be used without a formal demonstration of applicability as long as they are used as indicated in each model summary in appendix A. Further recommendations for the application of preferred models to specific source applications are found in subsequent sections of the *Guideline*.

b. If changes are made to a preferred model without affecting the modeled concentrations, the preferred status of the model is unchanged. Examples of modifications that do not affect concentrations are those made to enable use of a different computer platform or those that only affect the format or averaging time of the model results. The integration of a graphical user interface (GUI) to facilitate setting up the model inputs and/or analyzing the model results without otherwise altering the

preferred model code is another example of a modification that does not affect concentrations. However, when any changes are made, the Regional Administrator must require a test case example to demonstrate that the modeled concentrations are not affected.

c. A preferred model must be operated with the options listed in appendix A for its intended regulatory application. If the regulatory options are not applied, the model is no longer "preferred." Any other modification to a preferred model that would result in a change in the concentration estimates likewise alters its status so that it is no longer a preferred model. Use of the modified model must then be justified as an alternative model on a case-by-case basis to the appropriate reviewing authority and approved by the Regional Administrator.

d. Where the EPA has not identified a preferred model for a particular pollutant or situation, the EPA may establish a multi-tiered approach for making a demonstration required under PSD or another CAA program. The initial tier or tiers may involve use of demonstration tools, screening models, screening techniques, or reduced-form models; while the last tier may involve the use of demonstration tools, refined models or techniques, or alternative models approved under section 3.2.

### 3.2 Alternative Models

#### 3.2.1 Discussion

a. Selection of the best model or techniques for each individual air quality analysis is always encouraged, but the selection should be done in a consistent manner. A simple listing of models in this *Guideline* cannot alone achieve that consistency nor can it necessarily provide the best model for all possible situations. As discussed in section 3.1.1, the EPA has determined and applied a specific evaluation protocol that provides a statistical technique for evaluating model performance for predicting peak concentration values, as might be observed at individual monitoring locations.<sup>29</sup> This protocol is available to assist in developing a consistent approach when justifying the use of other-than-preferred models recommended in the *Guideline* (i.e., alternative models). The procedures in this protocol provide a general framework for objective decision-making on the acceptability of an alternative model for a given regulatory application. These objective procedures may be used for conducting both the technical evaluation of the model and the field test or performance evaluation.

b. This subsection discusses the use of alternate models and defines three situations when alternative models may be used. This subsection also provides a procedure for implementing 40 CFR 51.166(l)(2) in PSD permitting. This provision requires written approval of the Administrator for any modification or substitution of an applicable model. An applicable model for purposes of 40 CFR 51.166(l) is a preferred model in appendix A to the *Guideline*. Approval to use an alternative model under section 3.2 of the *Guideline* qualifies as approval for the modification or substitution of a model under 40 CFR 51.166(l)(2). The Regional

Administrators have delegated authority to issue such approvals under section 3.2 of the *Guideline*, provided that such approval is issued after consultation with the EPA's Model Clearinghouse and formally documented in a concurrence memorandum from the EPA's Model Clearinghouse which demonstrates that the requirements within section 3.2 for use of an alternative model have been met.

#### 3.2.2 Requirements

a. Determination of acceptability of an alternative model is an EPA Regional Office responsibility in consultation with the EPA's Model Clearinghouse as discussed in paragraphs 3.0(b) and 3.2.1(b). Where the Regional Administrator finds that an alternative model is more appropriate than a preferred model, that model may be used subject to the approval of the EPA Regional Office based on the requirements of this subsection. This finding will normally result from a determination that: (1) A preferred air quality model is not appropriate for the particular application; or (2) a more appropriate model or technique is available and applicable.

b. An alternative model shall be evaluated from both a theoretical and a performance perspective before it is selected for use. There are three separate conditions under which such a model may be approved for use:

1. If a demonstration can be made that the model produces concentration estimates equivalent to the estimates obtained using a preferred model;
2. If a statistical performance evaluation has been conducted using measured air quality data and the results of that evaluation indicate the alternative model performs better for the given application than a comparable model in appendix A; or
3. If there is no preferred model.

Any one of these three separate conditions may justify use of an alternative model. Some known alternative models that are applicable for selected situations are listed on the EPA's SCRAM Web site (section 2.3). However, inclusion there does not confer any unique status relative to other alternative models that are being or will be developed in the future.

c. Equivalency, condition (1) in paragraph (b) of this subsection, is established by demonstrating that the appropriate regulatory metric(s) are within  $\pm 2$  percent of the estimates obtained from the preferred model. The option to show equivalency is intended as a simple demonstration of acceptability for an alternative model that is nearly identical (or contains options that can make it identical) to a preferred model that it can be treated for practical purposes as the preferred model. However, notwithstanding this demonstration, models that are not equivalent may be used when one of the two other conditions described in paragraphs (d) and (e) of this subsection are satisfied.

d. For condition (2) in paragraph (b) of this subsection, established statistical performance evaluation procedures and techniques<sup>28,29</sup> for determining the acceptability of a model for an individual case based on superior performance should be followed, as appropriate. Preparation and

implementation of an evaluation protocol that is acceptable to both control agencies and regulated industry is an important element in such an evaluation.

e. Finally, for condition (3) in paragraph (b) of this subsection, an alternative model or technique may be approved for use provided that:

- i. The model or technique has received a scientific peer review;
  - ii. The model or technique can be demonstrated to be applicable to the problem on a theoretical basis;
  - iii. The databases which are necessary to perform the analysis are available and adequate;
  - iv. Appropriate performance evaluations of the model or technique have shown that the model or technique is not inappropriately biased for regulatory application<sup>a</sup>; and
  - v. A protocol on methods and procedures to be followed has been established.
- f. To formally document that the requirements of section 3.2 for use of an alternative model are satisfied for a particular application or range of applications, a memorandum will be prepared by the EPA's Model Clearinghouse through a consultative process with the EPA Regional Office.

### 3.3 EPA's Model Clearinghouse

a. The Regional Administrator has the authority to select models that are appropriate for use in a given situation. However, there is a need for assistance and guidance in the selection process so that fairness, consistency, and transparency in modeling decisions are fostered among the EPA Regional Offices and the state, local, and tribal agencies. To satisfy that need, the EPA established the Model Clearinghouse<sup>23</sup> to serve a central role of coordination and collaboration between EPA headquarters and the EPA Regional Offices. Additionally, the EPA holds periodic workshops with EPA Headquarters, EPA Regional Offices, and state, local, and tribal agency modeling representatives.

b. The appropriate EPA Regional Office should always be consulted for information and guidance concerning modeling methods and interpretations of modeling guidance, and to ensure that the air quality model user has available the latest most up-to-date policy and procedures. As appropriate, the EPA Regional Office may also request assistance from the EPA's Model Clearinghouse on other applications of models, analytical techniques, or databases or to clarify interpretation of the *Guideline* or related modeling guidance.

c. The EPA Regional Office will coordinate with the EPA's Model Clearinghouse after an initial evaluation and decision has been developed concerning the application of an alternative model. The acceptability and formal approval process for an alternative model is described in section 3.2.

<sup>a</sup> For PSD and other applications that use the model results in an absolute sense, the model should not be biased toward underestimates. Alternatively, for ozone and PM<sub>2.5</sub> SIP attainment demonstrations and other applications that use the model results in a relative sense, the model should not be biased toward overestimates.

#### 4.0 Models for Carbon Monoxide, Lead, Sulfur Dioxide, Nitrogen Dioxide and Primary Particulate Matter

##### 4.1 Discussion

a. This section identifies modeling approaches generally used in the air quality impact analysis of sources that emit the criteria pollutants carbon monoxide (CO), lead, sulfur dioxide (SO<sub>2</sub>), nitrogen dioxide (NO<sub>2</sub>), and primary particulates (PM<sub>2.5</sub> and PM<sub>10</sub>).

b. The guidance in this section is specific to the application of the Gaussian plume models identified in appendix A. Gaussian plume models assume that emissions and meteorology are in a steady-state, which is typically based on an hourly time step. This approach results in a plume that has an hourly-averaged distribution of emission mass according to a Gaussian curve through the plume. Though Gaussian steady-state models conserve the mass of the primary pollutant throughout the plume, they can still take into account a limited consideration of first-order removal processes (*e.g.*, wet and dry deposition) and limited chemical conversion (*e.g.*, OH oxidation).

c. Due to the steady-state assumption, Gaussian plume models are generally considered applicable to distances less than 50 km, beyond which, modeled predictions of plume impact are likely conservative. The locations of these impacts are expected to be unreliable due to changes in meteorology that are likely to occur during the travel time.

d. The applicability of Gaussian plume models may vary depending on the topography of the modeling domain, *i.e.*, simple or complex. Simple terrain is considered to be an area where terrain features are all lower in elevation than the top of the stack(s) of the source(s) in question. Complex terrain is defined as terrain exceeding the height of the stack(s) being modeled.

e. Gaussian models determine source impacts at discrete locations (receptors) for each meteorological and emission scenario, and generally attempt to estimate concentrations at specific sites that represent an ensemble average of numerous repetitions of the same "event." Uncertainties in model estimates are driven by this formulation, and as noted in section 2.1.1, evaluations of model accuracy should focus on the reducible uncertainty associated with physics and the formulation of the model. The "irreducible" uncertainty associated with Gaussian plume models may be responsible for variation in concentrations of as much as  $\pm 50$  percent.<sup>30</sup> "Reducible" uncertainties<sup>36</sup> can be on a similar scale. For example, Pasquill<sup>31</sup> estimates that, apart from data input errors, maximum ground-level concentrations at a given hour for a point source in flat terrain could be in error by 50 percent due to these uncertainties. Errors of 5 to 10 degrees in the measured wind direction can result in concentration errors of 20 to 70 percent for a particular time and location, depending on stability and station location. Such uncertainties do not indicate that an estimated concentration does not occur, only that the precise time and locations are in doubt. Composite errors in

highest estimated concentrations of 10 to 40 percent are found to be typical.<sup>32,33</sup> However, estimates of concentrations paired in time and space with observed concentrations are less certain.

f. Model evaluations and inter-comparisons should take these aspects of uncertainty into account. For a regulatory application of a model, the emphasis of model evaluations is generally placed on the highest modeled impacts. Thus, the Cox-Tikvart model evaluation approach, which compares the highest modeled impacts on several timescales, is recommended for comparisons of models and measurements and model inter-comparisons. The approach includes bootstrap techniques to determine the significance of various modeled predictions and increases the robustness of such comparisons when the number of available measurements are limited.<sup>34,35</sup> Because of the uncertainty in paired modeled and observed concentrations, any attempts at calibration of models based on these comparisons is of questionable benefit and shall not be done.

##### 4.2 Requirements

a. For NAAQS compliance demonstrations under PSD, use of the screening and preferred models for the pollutants listed in this subsection shall be limited to the near-field at a nominal distance of 50 km or less. Near-field application is consistent with capabilities of Gaussian plume models and, based on the EPA's assessment, is sufficient to address whether a source will cause or contribute to ambient concentrations in excess of a NAAQS. In most cases, maximum source impacts of inert pollutants will occur within the first 10 to 20 km from the source. Therefore, the EPA does not consider a long-range transport assessment beyond 50 km necessary for these pollutants if a near-field NAAQS compliance demonstration is required.<sup>36</sup>

b. For assessment of PSD increments within the near-field distance of 50 km or less, use of the screening and preferred models for the pollutants listed in this subsection shall be limited to the same screening and preferred models approved for NAAQS compliance demonstrations.

c. To determine if a compliance demonstration for NAAQS and/or PSD increments may be necessary beyond 50 km (*i.e.*, long-range transport assessment), the following screening approach shall be used to determine if a significant ambient impact will occur with particular focus on Class I areas and/or the applicable receptors that may be threatened at such distances.

i. Based on application in the near-field of the appropriate screening and/or preferred model, determine the significance of the ambient impacts at or about 50 km from the new or modifying source. If a near-field assessment is not available or this initial analysis indicates there may be significant ambient impacts at that distance, then further assessment is necessary.

ii. For assessment of the significance of ambient impacts for NAAQS and/or PSD increments, there is not a preferred model or screening approach for distances beyond 50 km. Thus, the appropriate reviewing authority (paragraph 3.0(b)) and the EPA

Regional Office shall be consulted in determining the appropriate and agreed upon screening technique to conduct the second level assessment. Typically, a Lagrangian model is most appropriate to use for these second level assessments, but applicants shall reach agreement on the specific model and modeling parameters on a case-by-case basis in consultation with the appropriate reviewing authority (paragraph 3.0(b)) and EPA Regional Office. When Lagrangian models are used in this manner, they shall not include plume-depleting processes, such that model estimates are considered conservative, as is generally appropriate for screening assessments.

d. In those situations where a cumulative impact analysis for NAAQS and/or PSD increments analysis beyond 50 km is necessary, the selection and use of an alternative model shall occur in agreement with the appropriate reviewing authority (paragraph 3.0(b)) and approval by the EPA Regional Office based on the requirements of paragraph 3.2.2(e).

##### 4.2.1 Screening Models and Techniques

a. Where a preliminary or conservative estimate is desired, point source screening techniques are an acceptable approach to air quality analyses.

b. As discussed in paragraph 2.2(a), screening models or techniques are designed to provide a conservative estimate of concentrations. The screening models used in most applications are the screening versions of the preferred models for refined applications. The two screening models, AERSCREEN<sup>37,38</sup> and CTSCREEN, are screening versions of AERMOD (American Meteorological Society (AMS)/EPA Regulatory Model) and CTDMPLUS (Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations), respectively. AERSCREEN is the recommended screening model for most applications in all types of terrain and for applications involving building downwash. For those applications in complex terrain where the application involves a well-defined hill or ridge, CTSCREEN<sup>39</sup> can be used.

c. Although AERSCREEN and CTSCREEN are designed to address a single-source scenario, there are approaches that can be used on a case-by-case basis to address multi-source situations using screening meteorology or other conservative model assumptions. However, the appropriate reviewing authority (paragraph 3.0(b)) shall be consulted, and concurrence obtained, on the protocol for modeling multiple sources with AERSCREEN or CTSCREEN to ensure that the worst case is identified and assessed.

d. As discussed in section 4.2.3.4, there are also screening techniques built into AERMOD that use simplified or limited chemistry assumptions for determining the partitioning of NO and NO<sub>2</sub> for NO<sub>2</sub> modeling. These screening techniques are part of the EPA's preferred modeling approach for NO<sub>2</sub> and do not need to be approved as an alternative model. However, as with other screening models and techniques, their usage shall occur in agreement with the appropriate reviewing authority (paragraph 3.0(b)).

e. As discussed in section 4.2(c)(ii), there are screening techniques needed for long-range transport assessments that will typically involve the use of a Lagrangian model. Based on the long-standing practice and documented capabilities of these models for long-range transport assessments, the use of a Lagrangian model as a screening technique for this purpose does not need to be approved as an alternative model. However, their usage shall occur in consultation with the appropriate reviewing authority (paragraph 3.0(b)) and EPA Regional Office.

f. All screening models and techniques shall be configured to appropriately address the site and problem at hand. Close attention must be paid to whether the area should be classified urban or rural in accordance with section 7.2.1.1. The climatology of the area must be studied to help define the worst-case meteorological conditions. Agreement shall be reached between the model user and the appropriate reviewing authority (paragraph 3.0(b)) on the choice of the screening model or technique for each analysis, on the input data and model settings, and the appropriate metric for satisfying regulatory requirements.

#### 4.2.1.1 AERSCREEN

a. Released in 2011, AERSCREEN is the EPA's recommended screening model for simple and complex terrain for single sources including point sources, area sources, horizontal stacks, capped stacks, and flares. AERSCREEN runs AERMOD in a screening mode and consists of two main components: 1) the MAKEMET program which generates a site-specific matrix of meteorological conditions for input to the AERMOD model; and 2) the AERSCREEN command-prompt interface.

b. The MAKEMET program generates a matrix of meteorological conditions, in the form of AERMOD-ready surface and profile files, based on user-specified surface characteristics, ambient temperatures, minimum wind speed, and anemometer height. The meteorological matrix is generated based on looping through a range of wind speeds, cloud covers, ambient temperatures, solar elevation angles, and convective velocity scales ( $w^*$ , for convective conditions only) based on user-specified surface characteristics for surface roughness ( $Z_s$ ), Bowen ratio ( $B_s$ ), and albedo ( $\alpha$ ). For unstable cases, the convective mixing height ( $Z_{c,c}$ ) is calculated based on  $w^*$ , and the mechanical mixing height ( $Z_{i,m}$ ) is calculated for unstable and stable conditions based on the friction velocity,  $u^*$ .

c. For applications involving simple or complex terrain, AERSCREEN interfaces with AERMAP. AERSCREEN also interfaces with BPIPFRM to provide the necessary building parameters for applications involving building downwash using the Plume Rise Model Enhancements (PRIME) downwash algorithm. AERSCREEN generates inputs to AERMOD via MAKEMET, AERMAP, and BPIPFRM and invokes AERMOD in a screening mode. The screening mode of AERMOD forces the AERMOD model calculations to represent values for the plume centerline, regardless of the source-receptor-wind direction orientation. The maximum concentration output from AERSCREEN

represents a worst-case 1-hour concentration. Averaging-time scaling factors of 1.0 for 3-hour, 0.9 for 8-hour, 0.60 for 24-hour, and 0.10 for annual concentration averages are applied internally by AERSCREEN to the highest 1-hour concentration calculated by the model for non-area type sources. For area type source concentrations for averaging times greater than one hour, the concentrations are equal to the 1-hour estimates.<sup>37,40</sup>

#### 4.2.1.2 CTSCREEN

a. CTSCREEN<sup>39,41</sup> can be used to obtain conservative, yet realistic, worst-case estimates for receptors located on terrain above stack height. CTSCREEN accounts for the three-dimensional nature of plume and terrain interaction and requires detailed terrain data representative of the modeling domain. The terrain data must be digitized in the same manner as for CTDMPUS and a terrain processor is available.<sup>42</sup> CTSCREEN is designed to execute a fixed matrix of meteorological values for wind speed ( $u$ ), standard deviation of horizontal and vertical wind speeds ( $\sigma_v$ ,  $\sigma_w$ ), vertical potential temperature gradient ( $d\theta/dz$ ), friction velocity ( $u^*$ ), Monin-Obukhov length ( $L$ ), mixing height ( $z_i$ ) as a function of terrain height, and wind directions for both neutral/stable conditions and unstable convective conditions. The maximum concentration output from CTSCREEN represents a worst-case 1-hour concentration. Time-scaling factors of 0.7 for 3-hour, 0.15 for 24-hour and 0.03 for annual concentration averages are applied internally by CTSCREEN to the highest 1-hour concentration calculated by the model.

#### 4.2.1.3 Screening in Complex Terrain

a. For applications utilizing AERSCREEN, AERSCREEN automatically generates a polar-grid receptor network with spacing determined by the maximum distance to model. If the application warrants a different receptor network than that generated by AERSCREEN, it may be necessary to run AERMOD in screening mode with a user-defined network. For CTSCREEN applications or AERMOD in screening mode outside of AERSCREEN, placement of receptors requires very careful attention when modeling in complex terrain. Often the highest concentrations are predicted to occur under very stable conditions, when the plume is near or impinges on the terrain. Under such conditions, the plume may be quite narrow in the vertical, so that even relatively small changes in a receptor's location may substantially affect the predicted concentration. Receptors within about a kilometer of the source may be even more sensitive to location. Thus, a dense array of receptors may be required in some cases.

b. For applications involving AERSCREEN, AERSCREEN interfaces with AERMAP to generate the receptor elevations. For applications involving CTSCREEN, digitized contour data must be preprocessed<sup>42</sup> to provide hill shape parameters in suitable input format. The user then supplies receptor locations either through an interactive program that is part of the model or directly, by using a text editor; using both methods to

select receptor locations will generally be necessary to assure that the maximum concentrations are estimated by either model. In cases where a terrain feature may "appear to the plume" as smaller, multiple hills, it may be necessary to model the terrain both as a single feature and as multiple hills to determine design concentrations.

c. Other screening techniques may be acceptable for complex terrain cases where established procedures<sup>43</sup> are used. The user is encouraged to confer with the appropriate reviewing authority (paragraph 3.0(b)) if any unforeseen problems are encountered, e.g., applicability, meteorological data, receptor siting, or terrain contour processing issues.

#### 4.2.2 Refined Models

a. A brief description of each preferred model for refined applications is found in appendix A. Also listed in that appendix are availability, the model input requirements, the standard options that shall be selected when running the program, and output options.

##### 4.2.2.1 AERMOD

a. For a wide range of regulatory applications in all types of terrain, and for aerodynamic building downwash, the required model is AERMOD.<sup>44,45</sup> The AERMOD regulatory modeling system consists of the AERMOD dispersion model, the AERMET meteorological processor, and the AERMAP terrain processor. AERMOD is a steady-state Gaussian plume model applicable to directly emitted air pollutants that employs best state-of-practice parameterizations for characterizing the meteorological influences and dispersion. Differentiation of simple versus complex terrain is unnecessary with AERMOD. In complex terrain, AERMOD employs the well-known dividing-streamline concept in a simplified simulation of the effects of plume-terrain interactions.

b. The AERMOD modeling system has been extensively evaluated across a wide range of scenarios based on numerous field studies, including tall stacks in flat and complex terrain settings, sources subject to building downwash influences, and low-level non-buoyant sources.<sup>27</sup> These evaluations included several long-term field studies associated with operating plants as well as several intensive tracer studies. Based on these evaluations, AERMOD has shown consistently good performance, with "errors" in predicted versus observed peak concentrations, based on the Robust Highest Concentration (RHC) metric, consistently within the range of 10 to 40 percent (cited in paragraph 4.1(e)).

c. AERMOD incorporates the PRIME algorithm to account for enhanced plume growth and restricted plume rise for plumes affected by building wake effects.<sup>46</sup> The PRIME algorithm accounts for entrainment of plume mass into the cavity recirculation region, including re-entrainment of plume mass into the wake region beyond the cavity.

d. AERMOD incorporates the Buoyant Line and Point Source (BLP) Dispersion model to account for buoyant plume rise from line sources. The BLP option utilizes the standard meteorological inputs provided by the AERMET meteorological processor.

e. The state-of-the-science for modeling atmospheric deposition is evolving, new modeling techniques are continually being assessed, and their results are being compared with observations. Consequently, while deposition treatment is available in AERMOD, the approach taken for any purpose shall be coordinated with the appropriate reviewing authority (paragraph 3.0(b)).

#### 4.2.2.2 CTDMPPLUS

a. If the modeling application involves an elevated point source with a well-defined hill or ridge and a detailed dispersion analysis of the spatial pattern of plume impacts is of interest, CTDMPPLUS is available. CTDMPPLUS provides greater resolution of concentrations about the contour of the hill feature than does AERMOD through a different plume-terrain interaction algorithm.

#### 4.2.2.3 OCD

a. If the modeling application involves determining the impact of offshore emissions from point, area, or line sources on the air quality of coastal regions, the recommended model is the OCD (Offshore and Coastal Dispersion) Model. OCD is a straight-line Gaussian model that incorporates overwater plume transport and dispersion as well as changes that occur as the plume crosses the shoreline. OCD is also applicable for situations that involve platform building downwash.

#### 4.2.3 Pollutant Specific Modeling Requirements

##### 4.2.3.1 Models for Carbon Monoxide

a. Models for assessing the impact of CO emissions are needed to meet NSR requirements to address compliance with the CO NAAQS and to determine localized impacts from transportations projects. Examples include evaluating effects of point sources, congested roadway intersections and highways, as well as the cumulative effect of numerous sources of CO in an urban area.

b. The general modeling recommendations and requirements for screening models in section 4.2.1 and refined models in section 4.2.2 shall be applied for CO modeling. Given the relatively low CO background concentrations, screening techniques are likely to be adequate in most cases. In applying these recommendations and requirements, the existing 1992 EPA guidance for screening CO impacts from highways may be consulted.<sup>47</sup>

##### 4.2.3.2 Models for Lead

a. In January 1999 (40 CFR part 58, appendix D), the EPA gave notice that concern about ambient lead impacts was being shifted away from roadways and toward a focus on stationary point sources. Thus, models for assessing the impact of lead emissions are needed to meet NSR requirements to address compliance with the lead NAAQS and for SIP attainment demonstrations. The EPA has also issued guidance on siting ambient monitors in the vicinity of stationary point sources.<sup>48</sup> For lead, the SIP should contain an air quality analysis to determine the maximum rolling 3-month average lead concentration resulting from major lead point sources, such as

smelters, gasoline additive plants, etc. The EPA has developed a post-processor to calculate rolling 3-month average concentrations from model output.<sup>49</sup> General guidance for lead SIP development is also available.<sup>50</sup>

b. For major lead point sources, such as smelters, which contribute fugitive emissions and for which deposition is important, professional judgment should be used, and there shall be coordination with the appropriate reviewing authority (paragraph 3.0(b)). For most applications, the general requirements for screening and refined models of section 4.2.1 and 4.2.2 are applicable to lead modeling.

##### 4.2.3.3 Models for Sulfur Dioxide

a. Models for SO<sub>2</sub> are needed to meet NSR requirements to address compliance with the SO<sub>2</sub> NAAQS and PSD increments, for SIP attainment demonstrations,<sup>51</sup> and for characterizing current air quality via modeling.<sup>52</sup> SO<sub>2</sub> is one of a group of highly reactive gases known as "oxides of sulfur" with largest emissions sources being fossil fuel combustion at power plants and other industrial facilities.

b. Given the relatively inert nature of SO<sub>2</sub> on the short-term time scales of interest (*i.e.*, 1-hour) and the sources of SO<sub>2</sub> (*i.e.*, stationary point sources), the general modeling requirements for screening models in section 4.2.1 and refined models in section 4.2.2 are applicable for SO<sub>2</sub> modeling applications. For urban areas, AERMOD automatically invokes a half-life of 4 hours<sup>53</sup> to SO<sub>2</sub>. Therefore, care must be taken when determining whether a source is urban or rural (*see* section 7.2.1.1 for urban/rural determination methodology).

##### 4.2.3.4 Models for Nitrogen Dioxide

a. Models for assessing the impact of sources on ambient NO<sub>2</sub> concentrations are needed to meet NSR requirements to address compliance with the NO<sub>2</sub> NAAQS and PSD increments. Impact of an individual source on ambient NO<sub>2</sub> depends, in part, on the chemical environment into which the source's plume is to be emitted. This is due to the fact that NO<sub>2</sub> sources co-emit NO along with NO<sub>2</sub> and any emitted NO may react with ambient ozone to convert to additional NO<sub>2</sub> downwind. Thus, comprehensive modeling of NO<sub>2</sub> would need to consider the ratio of emitted NO and NO<sub>2</sub>, the ambient levels of ozone and subsequent reactions between ozone and NO, and the photolysis of NO<sub>2</sub> to NO.

b. Due to the complexity of NO<sub>2</sub> modeling, a multi-tiered screening approach is required to obtain hourly and annual average estimates of NO<sub>2</sub>.<sup>54</sup> Since these methods are considered screening techniques, their usage shall occur in agreement with the appropriate reviewing authority (paragraph 3.0(b)). Additionally, since screening techniques are conservative by their nature, there are limitations to how these options can be used. Specifically, modeling of negative emissions rates should only be done after consultation with the EPA Regional Office to ensure that decreases in concentrations would not be overestimated. Each tiered approach (*see* Figure 4–1) accounts for increasingly complex considerations of NO<sub>2</sub> chemistry

and is described in paragraphs c through e of this subsection. The tiers of NO<sub>2</sub> modeling include:

i. A first-tier (most conservative) "full" conversion approach;

ii. A second-tier approach that assumes ambient equilibrium between NO and NO<sub>2</sub>; and

iii. A third-tier consisting of several detailed screening techniques that account for ambient ozone and the relative amount of NO and NO<sub>2</sub> emitted from a source.

c. For Tier 1, use an appropriate refined model (section 4.2.2) to estimate nitrogen oxides (NO<sub>x</sub>) concentrations and assume a total conversion of NO to NO<sub>2</sub>.

d. For Tier 2, multiply the Tier 1 result(s) by the Ambient Ratio Method 2 (ARM2), which provides estimates of representative equilibrium ratios of NO<sub>2</sub>/NO<sub>x</sub> value based ambient levels of NO<sub>2</sub> and NO<sub>x</sub> derived from national data from the EPA's Air Quality System (AQS).<sup>55</sup> The national default for ARM2 includes a minimum ambient NO<sub>2</sub>/NO<sub>x</sub> ratio of 0.5 and a maximum ambient ratio of 0.9. The reviewing agency may establish alternative minimum ambient NO<sub>2</sub>/NO<sub>x</sub> values based on the source's in-stack emissions ratios, with alternative minimum ambient ratios reflecting the source's in-stack NO<sub>2</sub>/NO<sub>x</sub> ratios. Preferably, alternative minimum ambient NO<sub>2</sub>/NO<sub>x</sub> ratios should be based on source-specific data which satisfies all quality assurance procedures that ensure data accuracy for both NO<sub>2</sub> and NO<sub>x</sub> within the typical range of measured values. However, alternate information may be used to justify a source's anticipated NO<sub>2</sub>/NO<sub>x</sub> in-stack ratios, such as manufacturer test data, state or local agency guidance, peer-reviewed literature, and/or the EPA's NO<sub>2</sub>/NO<sub>x</sub> ratio database.

e. For Tier 3, a detailed screening technique shall be applied on a case-by-case basis. Because of the additional input data requirements and complexities associated with the Tier 3 options, their usage shall occur in consultation with the EPA Regional Office in addition to the appropriate reviewing authority. The Ozone Limiting Method (OLM)<sup>56</sup> and the Plume Volume Molar Ratio Method (PVMRM)<sup>57</sup> are two detailed screening techniques that may be used for most sources. These two techniques use an appropriate section 4.2.2 model to estimate NO<sub>x</sub> concentrations and then estimate the conversion of primary NO emissions to NO<sub>2</sub> based on the ambient levels of ozone and the plume characteristics. OLM only accounts for NO<sub>2</sub> formation based on the ambient levels of ozone while PVMRM also accommodates distance-dependent conversion ratios based on ambient ozone. Both PVMRM and OLM require that ambient ozone concentrations be provided on an hourly basis and explicit specification of the NO<sub>2</sub>/NO<sub>x</sub> in-stack ratios. PVMRM works best for relatively isolated and elevated point source modeling while OLM works best for large groups of sources, area sources, and near-surface releases, including roadway sources.

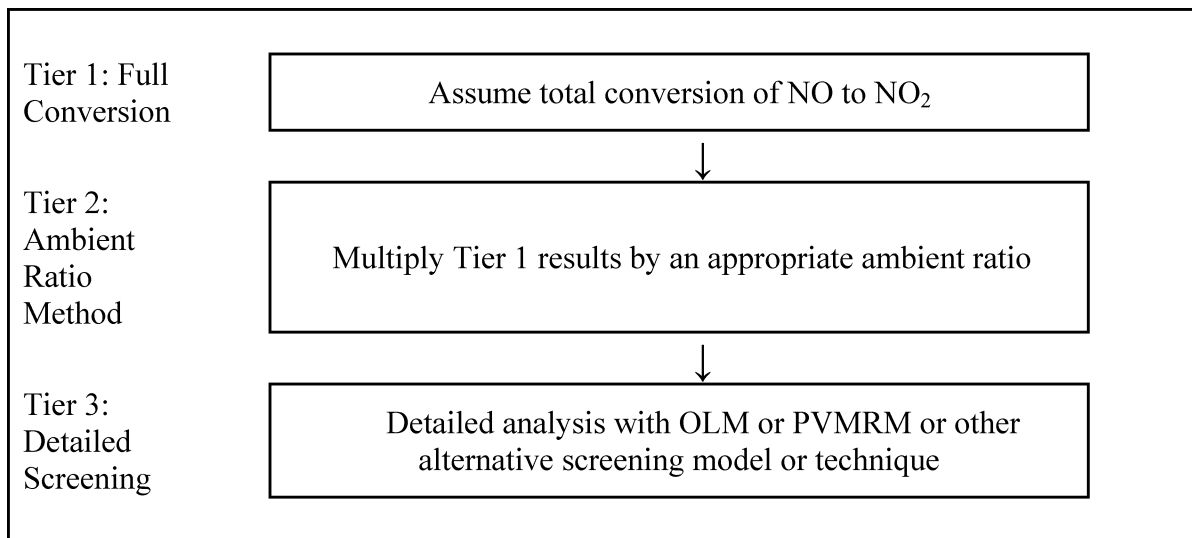
f. Alternative models or techniques may be considered on a case-by-case basis and their usage shall be approved by the EPA Regional Office (section 3.2). Such models or



techniques should consider individual quantities of NO and NO<sub>2</sub> emissions, atmospheric transport and dispersion, and

atmospheric transformation of NO to NO<sub>2</sub>. Dispersion models that account for more explicit photochemistry may also be

considered as an alternative model to estimate ambient impacts of NO<sub>x</sub> sources.



**Figure 4-1: Multi-tiered Approach for Estimating NO<sub>2</sub> Concentrations**

#### 4.2.3.5 Models for PM<sub>2.5</sub>

a. PM<sub>2.5</sub> is a mixture consisting of several diverse components.<sup>58</sup> Ambient PM<sub>2.5</sub> generally consists of two components: (1) The primary component, emitted directly from a source; and (2) the secondary component, formed in the atmosphere from other pollutants emitted from the source. Models for PM<sub>2.5</sub> are needed to meet NSR requirements to address compliance with the PM<sub>2.5</sub> NAAQS and PSD increments and for SIP attainment demonstrations.

b. For NSR modeling assessments, the general modeling requirements for screening models in section 4.2.1 and refined models in section 4.2.2 are applicable for the primary component of PM<sub>2.5</sub>, while the methods in section 5.4 are applicable for addressing the secondary component of PM<sub>2.5</sub>. Guidance for PSD assessments is available for determining the best approach to handling sources of primary and secondary PM<sub>2.5</sub>.<sup>59</sup>

c. For SIP attainment demonstrations and regional haze reasonable progress goal analyses, effects of a control strategy on PM<sub>2.5</sub> are estimated from the sum of the effects on the primary and secondary components composing PM<sub>2.5</sub>. Model users should refer to section 5.4.1 and associated SIP modeling guidance<sup>60</sup> for further details concerning appropriate modeling approaches.

d. The general modeling requirements for the refined models discussed in section 4.2.2 shall be applied for PM<sub>2.5</sub> hot-spot modeling for mobile sources. Specific guidance is available for analyzing direct PM<sub>2.5</sub> impacts from highways, terminals, and other transportation projects.<sup>61</sup>

#### 4.2.3.6 Models for PM<sub>10</sub>

a. Models for PM<sub>10</sub> are needed to meet NSR requirements to address compliance with the PM<sub>10</sub> NAAQS and PSD increments and for SIP attainment demonstrations.

b. For most sources, the general modeling requirements for screening models in section

4.2.1 and refined models in section 4.2.2 shall be applied for PM<sub>10</sub> modeling. In cases where the particle size and its effect on ambient concentrations need to be considered, particle deposition may be used on a case-by-case basis and their usage shall be coordinated with the appropriate reviewing authority. A SIP development guide<sup>62</sup> is also available to assist in PM<sub>10</sub> analyses and control strategy development.

c. Fugitive dust usually refers to dust put into the atmosphere by the wind blowing over plowed fields, dirt roads, or desert or sandy areas with little or no vegetation. Fugitive emissions include the emissions resulting from the industrial process that are not captured and vented through a stack, but may be released from various locations within the complex. In some unique cases, a model developed specifically for the situation may be needed. Due to the difficult nature of characterizing and modeling fugitive dust and fugitive emissions, the proposed procedure shall be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)) for each specific situation before the modeling exercise is begun. Re-entrained dust is created by vehicles driving over dirt roads (e.g., haul roads) and dust-covered roads typically found in arid areas. Such sources can be characterized as line, area or volume sources.<sup>63</sup> Emission rates may be based on site-specific data or values from the general literature.

d. Under certain conditions, recommended dispersion models may not be suitable to appropriately address the nature of ambient PM<sub>10</sub>. In these circumstances, the alternative modeling approach shall be approved by the EPA Regional Office (section 3.2).

e. The general modeling requirements for the refined models discussed in section 4.2.2 shall be applied for PM<sub>10</sub> hot-spot modeling for mobile sources. Specific guidance is available for analyzing direct PM<sub>10</sub> impacts

from highways, terminals, and other transportation projects.<sup>61</sup>

## 5.0 Models for Ozone and Secondary Formed Particulate Matter

### 5.1 Discussion

a. Air pollutants formed through chemical reactions in the atmosphere are referred to as secondary pollutants. For example, ground-level ozone and a portion of PM<sub>2.5</sub> are secondary pollutants formed through photochemical reactions. Ozone and secondarily formed particulate matter are closely related to each other in that they share common sources of emissions and are formed in the atmosphere from chemical reactions with similar precursors.

b. Ozone formation is driven by emissions of NO<sub>x</sub> and volatile organic compounds (VOCs). Ozone formation is a complicated nonlinear process that requires favorable meteorological conditions in addition to VOC and NO<sub>x</sub> emissions. Sometimes complex terrain features also contribute to the build-up of precursors and subsequent ozone formation or destruction.

c. PM<sub>2.5</sub> can be either primary (i.e., emitted directly from sources) or secondary in nature. The fraction of PM<sub>2.5</sub> which is primary versus secondary varies by location and season. In the United States, PM<sub>2.5</sub> is dominated by a variety of chemical species or components of atmospheric particles, such as ammonium sulfate, ammonium nitrate, organic carbon mass, elemental carbon, and other soil compounds and oxidized metals. PM<sub>2.5</sub> sulfate, nitrate, and ammonium ions are predominantly the result of chemical reactions of the oxidized products of SO<sub>2</sub> and NO<sub>x</sub> emissions with direct ammonia emissions.<sup>64</sup>

d. Control measures reducing ozone and PM<sub>2.5</sub> precursor emissions may not lead to proportional reductions in ozone and PM<sub>2.5</sub>. Modeled strategies designed to reduce ozone

or PM<sub>2.5</sub> levels typically need to consider the chemical coupling between these pollutants. This coupling is important in understanding processes that control the levels of both pollutants. Thus, when feasible, it is important to use models that take into account the chemical coupling between ozone and PM<sub>2.5</sub>. In addition, using such a multi-pollutant modeling system can reduce the resource burden associated with applying and evaluating separate models for each pollutant and promotes consistency among the strategies themselves.

e. PM<sub>2.5</sub> is a mixture consisting of several diverse chemical species or components of atmospheric particles. Because chemical and physical properties and origins of each component differ, it may be appropriate to use either a single model capable of addressing several of the important components or to model primary and secondary components using different models. Effects of a control strategy on PM<sub>2.5</sub> is estimated from the sum of the effects on the specific components comprising PM<sub>2.5</sub>.

## 5.2 Recommendations

a. Chemical transformations can play an important role in defining the concentrations and properties of certain air pollutants. Models that take into account chemical reactions and physical processes of various pollutants (including precursors) are needed for determining the current state of air quality, as well as predicting and projecting the future evolution of these pollutants. It is important that a modeling system provide a realistic representation of chemical and physical processes leading to secondary pollutant formation and removal from the atmosphere.

b. Chemical transport models treat atmospheric chemical and physical processes such as deposition and motion. There are two types of chemical transport models, Eulerian (grid based) and Lagrangian. These types of models are differentiated from each other by their frame of reference. Eulerian models are based on a fixed frame of reference and Lagrangian models use a frame of reference that moves with parcels of air between the source and receptor point.<sup>9</sup> Photochemical grid models are three-dimensional Eulerian grid-based models that treat chemical and physical processes in each grid cell and use diffusion and transport processes to move chemical species between grid cells.<sup>9</sup> These types of models are appropriate for assessment of near-field and regional scale reactive pollutant impacts from specific sources<sup>7 10 11 12</sup> or all sources.<sup>13 14 15</sup> In some limited cases, the secondary processes can be treated with a box model, ideally in combination with a number of other modeling techniques and/or analyses to treat individual source sectors.

c. Regardless of the modeling system used to estimate secondary impacts of ozone and/or PM<sub>2.5</sub>, model results should be compared to observation data to generate confidence that the modeling system is representative of the local and regional air quality. For ozone related projects, model estimates of ozone should be compared with observations in both time and space. For PM<sub>2.5</sub>, model estimates of speciated PM<sub>2.5</sub> components

(such as sulfate ion, nitrate ion, etc.) should be compared with observations in both time and space.<sup>65</sup>

d. Model performance metrics comparing observations and predictions are often used to summarize model performance. These metrics include mean bias, mean error, fractional bias, fractional error, and correlation coefficient.<sup>65</sup> There are no specific levels of any model performance metric that indicate "acceptable" model performance. The EPA's preferred approach for providing context about model performance is to compare model performance metrics with similar contemporary applications.<sup>60 65</sup> Because model application purpose and scope vary, model users should consult with the appropriate reviewing authority (paragraph 3.0(b)) to determine what model performance elements should be emphasized and presented to provide confidence in the regulatory model application.

e. There is no preferred modeling system or technique for estimating ozone or secondary PM<sub>2.5</sub> for specific source impacts or to assess impacts from multiple sources. For assessing secondary pollutant impacts from single sources, the degree of complexity required to assess potential impacts varies depending on the nature of the source, its emissions, and the background environment. The EPA recommends a two-tiered approach where the first tier consists of using existing technically credible and appropriate relationships between emissions and impacts developed from previous modeling that is deemed sufficient for evaluating a source's impacts. The second tier consists of more sophisticated case-specific modeling analyses. The appropriate tier for a given application should be selected in consultation with the appropriate reviewing authority (paragraph 3.0(b)) and be consistent with EPA guidance.<sup>66</sup>

## 5.3 Recommended Models and Approaches for Ozone

a. Models that estimate ozone concentrations are needed to guide the choice of strategies for the purposes of a nonattainment area demonstrating future year attainment of the ozone NAAQS. Additionally, models that estimate ozone concentrations are needed to assess impacts from specific sources or source complexes to satisfy requirements for NSR and other regulatory programs. Other purposes for ozone modeling include estimating the impacts of specific events on air quality, ozone deposition impacts, and planning for areas that may be attaining the ozone NAAQS.

### 5.3.1 Models for NAAQS Attainment Demonstrations and Multi-Source Air Quality Assessments

a. Simulation of ozone formation and transport is a complex exercise. Control agencies with jurisdiction over areas with ozone problems should use photochemical grid models to evaluate the relationship between precursor species and ozone. Use of photochemical grid models is the recommended means for identifying control strategies needed to address high ozone concentrations in such areas. Judgment on

the suitability of a model for a given application should consider factors that include use of the model in an attainment test, development of emissions and meteorological inputs to the model, and choice of episodes to model. Guidance on the use of models and other analyses for demonstrating attainment of the air quality goals for ozone is available.<sup>59 60</sup> Users should consult with the appropriate reviewing authority (paragraph 3.0(b)) to ensure the most current modeling guidance is applied.

### 5.3.2 Models for Single-Source Air Quality Assessments

a. Depending on the magnitude of emissions, estimating the impact of an individual source's emissions of NO<sub>x</sub> and VOC on ambient ozone is necessary for obtaining a permit. The simulation of ozone formation and transport requires realistic treatment of atmospheric chemistry and deposition. Models (*e.g.*, Lagrangian and photochemical grid models) that integrate chemical and physical processes important in the formation, decay, and transport of ozone and important precursor species should be applied. Photochemical grid models are primarily designed to characterize precursor emissions and impacts from a wide variety of sources over a large geographic area but can also be used to assess the impacts from specific sources.<sup>7 11 12</sup>

b. The first tier of assessment for ozone impacts involves those situations where existing technical information is available (*e.g.*, results from existing photochemical grid modeling, published empirical estimates of source specific impacts, or reduced-form models) in combination with other supportive information and analysis for the purposes of estimating secondary impacts from a particular source. The existing technical information should provide a credible and representative estimate of the secondary impacts from the project source. The appropriate reviewing authority (paragraph 3.0(b)) and appropriate EPA guidance<sup>66</sup> should be consulted to determine what types of assessments may be appropriate on a case-by-case basis.

c. The second tier of assessment for ozone impacts involves those situations where existing technical information is not available or a first tier demonstration indicates a more refined assessment is needed. For these situations, chemical transport models should be used to address single-source impacts. Special considerations are needed when using these models to evaluate the ozone impact from an individual source. Guidance on the use of models and other analyses for demonstrating the impacts of single sources for ozone is available.<sup>66</sup> This guidance document provides a more detailed discussion of the appropriate approaches to obtaining estimates of ozone impacts from a single source. Model users should use the latest version of the guidance in consultation with the appropriate reviewing authority (paragraph 3.0(b)) to determine the most suitable refined approach for single-source ozone modeling on a case-by-case basis.

#### 5.4 Recommended Models and Approaches for Secondarily Formed PM<sub>2.5</sub>

a. Models that estimate PM<sub>2.5</sub> concentrations are needed to guide the choice of strategies for the purposes of a nonattainment area demonstrating future year attainment of the PM<sub>2.5</sub> NAAQS. Additionally, models that estimate PM<sub>2.5</sub> concentrations are needed to assess impacts from specific sources or source complexes to satisfy requirements for NSR and other regulatory programs. Other purposes for PM<sub>2.5</sub> modeling include estimating the impacts of specific events on air quality, visibility, deposition impacts, and planning for areas that may be attaining the PM<sub>2.5</sub> NAAQS.

##### 5.4.1 Models for NAAQS Attainment Demonstrations and Multi-Source Air Quality Assessments

a. Models for PM<sub>2.5</sub> are needed to assess the adequacy of a proposed strategy for meeting the annual and 24-hour PM<sub>2.5</sub> NAAQS. Modeling primary and secondary PM<sub>2.5</sub> can be a multi-faceted and complex problem, especially for secondary components of PM<sub>2.5</sub> such as sulfates and nitrates. Control agencies with jurisdiction over areas with secondary PM<sub>2.5</sub> problems should use models that integrate chemical and physical processes important in the formation, decay, and transport of these species (e.g., photochemical grid models). Suitability of a modeling approach or mix of modeling approaches for a given application requires technical judgment as well as professional experience in choice of models, use of the model(s) in an attainment test, development of emissions and meteorological inputs to the model, and selection of days to model. Guidance on the use of models and other analyses for demonstrating attainment of the air quality goals for PM<sub>2.5</sub> is available.<sup>59, 60</sup> Users should consult with the appropriate reviewing authority (paragraph 3.0(b)) to ensure the most current modeling guidance is applied.

##### 5.4.2 Models for Single-Source Air Quality Assessments

a. Depending on the magnitude of emissions, estimating the impact of an individual source's emissions on secondary particulate matter concentrations may be necessary for obtaining a permit. Primary PM<sub>2.5</sub> components shall be simulated using the general modeling requirements in section 4.2.3.5. The simulation of secondary particulate matter formation and transport is a complex exercise requiring realistic treatment of atmospheric chemistry and deposition. Models should be applied that integrate chemical and physical processes important in the formation, decay, and transport of these species (e.g., Lagrangian and photochemical grid models). Photochemical grid models are primarily designed to characterize precursor emissions and impacts from a wide variety of sources over a large geographic area and can also be used to assess the impacts from specific sources.<sup>7, 10</sup> For situations where a project source emits both primary PM<sub>2.5</sub> and PM<sub>2.5</sub> precursors, the contribution from both should be combined for use in determining the source's ambient impact. Approaches for

combining primary and secondary impacts are provided in appropriate guidance for single source permit related demonstrations.<sup>66</sup>

b. The first tier of assessment for secondary PM<sub>2.5</sub> impacts involves those situations where existing technical information is available (e.g., results from existing photochemical grid modeling, published empirical estimates of source specific impacts, or reduced-form models) in combination with other supportive information and analysis for the purposes of estimating secondary impacts from a particular source. The existing technical information should provide a credible and representative estimate of the secondary impacts from the project source. The appropriate reviewing authority (paragraph 3.0(b)) and appropriate EPA guidance<sup>66</sup> should be consulted to determine what types of assessments may be appropriate on a case-by-case basis.

c. The second tier of assessment for secondary PM<sub>2.5</sub> impacts involves those situations where existing technical information is not available or a first tier demonstration indicates a more refined assessment is needed. For these situations, chemical transport models should be used for assessments of single-source impacts. Special considerations are needed when using these models to evaluate the secondary particulate matter impact from an individual source. Guidance on the use of models and other analyses for demonstrating the impacts of single sources for secondary PM<sub>2.5</sub> is available.<sup>66</sup> This guidance document provides a more detailed discussion of the appropriate approaches to obtaining estimates of secondary particulate matter concentrations from a single source. Model users should use the latest version of this guidance in consultation with the appropriate reviewing authority (paragraph 3.0(b)) to determine the most suitable single-source modeling approach for secondary PM<sub>2.5</sub> on a case-by-case basis.

## 6.0 Modeling for Air Quality Related Values and Other Governmental Programs

### 6.1 Discussion

a. Other federal government agencies and state, local, and tribal agencies with air quality and land management responsibilities have also developed specific modeling approaches for their own regulatory or other requirements. Although such regulatory requirements and guidance have come about because of EPA rules or standards, the implementation of such regulations and the use of the modeling techniques is under the jurisdiction of the agency issuing the guidance or directive. This section covers such situations with reference to those guidance documents, when they are available.

b. When using the model recommended or discussed in the *Guideline* in support of programmatic requirements not specifically covered by EPA regulations, the model user should consult the appropriate federal, state, local, or tribal agency to ensure the proper application and use of the models and/or techniques. These agencies have developed specific modeling approaches for their own

regulatory or other requirements. Most of the programs have, or will have when fully developed, separate guidance documents that cover the program and a discussion of the tools that are needed. The following paragraphs reference those guidance documents, when they are available.

### 6.2 Air Quality Related Values

a. The 1990 CAA Amendments give FLMs an "affirmative responsibility" to protect the natural and cultural resources of Class I areas from the adverse impacts of air pollution and to provide the appropriate procedures and analysis techniques. The CAA identifies the FLM as the Secretary of the department, or their designee, with authority over these lands. Mandatory Federal Class I areas are defined in the CAA as international parks, national parks over 6,000 acres, and wilderness areas and memorial parks over 5,000 acres, established as of 1977. The FLMs are also concerned with the protection of resources in federally managed Class II areas because of other statutory mandates to protect these areas. Where state or tribal agencies have successfully petitioned the EPA and lands have been redesignated to Class I status, these agencies may have equivalent responsibilities to that of the FLMs for these non-federal Class I areas as described throughout the remainder of section 6.2.

b. The FLM agency responsibilities include the review of air quality permit applications from proposed new or modified major pollution sources that may affect these Class I areas to determine if emissions from a proposed or modified source will cause or contribute to adverse impacts on air quality related values (AQRVs) of a Class I area and making recommendations to the FLM. AQRVs are resources, identified by the FLM agencies, that have the potential to be affected by air pollution. These resources may include visibility, scenic, cultural, physical, or ecological resources for a particular area. The FLM agencies take into account the particular resources and AQRVs that would be affected; the frequency and magnitude of any potential impacts; and the direct, indirect, and cumulative effects of any potential impacts in making their recommendations.

c. While the AQRV notification and impact analysis requirements are outlined in the PSD regulations at 40 CFR 51.166(p) and 40 CFR 52.21(p), determination of appropriate analytical methods and metrics for AQRV's are determined by the FLM agencies and are published in guidance external to the general recommendations of this paragraph.

d. To develop greater consistency in the application of air quality models to assess potential AQRV impacts in both Class I areas and protected Class II areas, the FLM agencies have developed the Federal Land Managers' Air Quality Related Values Work Group Phase I Report (FLAG).<sup>67</sup> FLAG focuses upon specific technical and policy issues associated with visibility impairment, effects of pollutant deposition on soils and surface waters, and ozone effects on vegetation. Model users should consult the latest version of the FLAG report for current modeling guidance and with affected FLM

agency representatives for any application specific guidance which is beyond the scope of the *Guideline*.

#### 6.2.1 Visibility

a. Visibility in important natural areas (e.g., Federal Class I areas) is protected under a number of provisions of the CAA, including sections 169A and 169B (addressing impacts primarily from existing sources) and section 165 (new source review). Visibility impairment is caused by light scattering and light absorption associated with particles and gases in the atmosphere. In most areas of the country, light scattering by PM<sub>2.5</sub> is the most significant component of visibility impairment. The key components of PM<sub>2.5</sub> contributing to visibility impairment include sulfates, nitrates, organic carbon, elemental carbon, and crustal material.<sup>67</sup>

b. Visibility regulations (40 CFR 51.300 through 51.309) require state, local, and tribal agencies to mitigate current and prevent future visibility impairment in any of the 156 mandatory Federal Class I areas where visibility is considered an important attribute. In 1999, the EPA issued revisions to the regulations to address visibility impairment in the form of regional haze, which is caused by numerous, diverse sources (e.g., stationary, mobile, and area sources) located across a broad region (40 CFR 51.308 through 51.309). The state of relevant scientific knowledge has expanded significantly since that time. A number of studies and reports<sup>68 69</sup> have concluded that long-range transport (e.g., up to hundreds of kilometers) of fine particulate matter plays a significant role in visibility impairment across the country. Section 169A of the CAA requires states to develop SIPs containing long-term strategies for remedying existing and preventing future visibility impairment in the 156 mandatory Class I Federal areas, where visibility is considered an important attribute. In order to develop long-term strategies to address regional haze, many state, local, and tribal agencies will need to conduct regional-scale modeling of fine particulate concentrations and associated visibility impairment.

c. The FLAG visibility modeling recommendations are divided into two distinct sections to address different requirements for: (1) Near field modeling where plumes or layers are compared against a viewing background, and (2) distant/multi-source modeling for plumes and aggregations of plumes that affect the general appearance of a scene.<sup>67</sup> The recommendations separately address visibility assessments for sources proposing to locate relatively near and at farther distances from these areas.<sup>67</sup>

##### 6.2.1.1 Models for Estimating Near-Field Visibility Impairment

a. To calculate the potential impact of a plume of specified emissions for specific transport and dispersion conditions ("plume blight") for source-receptor distances less than 50 km, a screening model and guidance are available.<sup>67 70</sup> If a more comprehensive analysis is necessary, a refined model should be selected. The model selection, procedures, and analyses should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)) and the affected FLM(s).

##### 6.2.1.2 Models for Estimating Visibility Impairment for Long-Range Transport

a. Chemical transformations can play an important role in defining the concentrations and properties of certain air pollutants. Models that take into account chemical reactions and physical processes of various pollutants (including precursors) are needed for determining the current state of air quality, as well as predicting and projecting the future evolution of these pollutants. It is important that a modeling system provide a realistic representation of chemical and physical processes leading to secondary pollutant formation and removal from the atmosphere.

b. Chemical transport models treat atmospheric chemical and physical processes such as deposition and motion. There are two types of chemical transport models, Eulerian (grid based) and Lagrangian. These types of models are differentiated from each other by their frame of reference. Eulerian models are based on a fixed frame of reference and Lagrangian models use a frame of reference that moves with parcels of air between the source and receptor point.<sup>9</sup> Photochemical grid models are three-dimensional Eulerian grid-based models that treat chemical and physical processes in each grid cell and use diffusion and transport processes to move chemical species between grid cells.<sup>9</sup> These types of models are appropriate for assessment of near-field and regional scale reactive pollutant impacts from specific sources<sup>7 10 11 12</sup> or all sources.<sup>13 14 15</sup>

c. Development of the requisite meteorological and emissions databases necessary for use of photochemical grid models to estimate AQRVs should conform to recommendations in section 8 and those outlined in the EPA's *Modeling Guidance for Demonstrating Attainment of Air Quality Goals for Ozone, PM<sub>2.5</sub>, and Regional Haze*.<sup>60</sup> Demonstration of the adequacy of prognostic meteorological fields can be established through appropriate diagnostic and statistical performance evaluations consistent with recommendations provided in the appropriate guidance.<sup>60</sup> Model users should consult the latest version of this guidance and with the appropriate reviewing authority (paragraph 3.0(b)) for any application-specific guidance that is beyond the scope of this subsection.

##### 6.2.2 Models for Estimating Deposition Impacts

a. For many Class I areas, AQRVs have been identified that are sensitive to atmospheric deposition of air pollutants. Emissions of NO<sub>x</sub>, sulfur oxides, NH<sub>3</sub>, mercury, and secondary pollutants such as ozone and particulate matter affect components of ecosystems. In sensitive ecosystems, these compounds can acidify soils and surface waters, add nutrients that change biodiversity, and affect the ecosystem services provided by forests and natural areas.<sup>67</sup> To address the relationship between deposition and ecosystem effects, the FLM agencies have developed estimates of critical loads. A critical load is defined as, "A quantitative estimate of an exposure to one or more pollutants below which significant harmful effects on specified sensitive

elements of the environment do not occur according to present knowledge."<sup>71</sup>

b. The FLM deposition modeling recommendations are divided into two distinct sections to address different requirements for: (1) Near field modeling, and (2) distant/multi-source modeling for cumulative effects. The recommendations separately address deposition assessments for sources proposing to locate relatively near and at farther distances from these areas.<sup>67</sup> Where the source and receptors are not in close proximity, chemical transport (e.g., photochemical grid) models generally should be applied for an assessment of deposition impacts due to one or a small group of sources. Over these distances, chemical and physical transformations can change atmospheric residence time due to different propensity for deposition to the surface of different forms of nitrate and sulfate. Users should consult the latest version of the FLAG report<sup>67</sup> and relevant FLM representatives for guidance on the use of models for deposition. Where source and receptors are in close proximity, users should contact the appropriate FLM for application-specific guidance.

##### 6.3 Modeling Guidance for Other Governmental Programs

a. Dispersion and photochemical grid modeling may need to be conducted to ensure that individual and cumulative offshore oil and gas exploration, development, and production plans and activities do not significantly affect the air quality of any state as required under the Outer Continental Shelf Lands Act (OCSLA). Air quality modeling requires various input datasets, including emissions sources, meteorology, and pre-existing pollutant concentrations. For sources under the reviewing authority of the Department of Interior, Bureau of Ocean Energy Management (BOEM), guidance for the development of all necessary Outer Continental Shelf (OCS) air quality modeling inputs and appropriate model selection and application is available from the BOEM's Web site: <https://www.boem.gov/GOMR-Environmental-Compliance>.

b. The Federal Aviation Administration (FAA) is the appropriate reviewing authority for air quality assessments of primary pollutant impacts at airports and air bases. The Aviation Environmental Design Tool (AEDT) is developed and supported by the FAA, and is appropriate for air quality assessment of primary pollutant impacts at airports or air bases. AEDT has adopted AERMOD for treating dispersion. Application of AEDT is intended for estimating the change in emissions for aircraft operations, point source, and mobile source emissions on airport property and quantify the associated pollutant level- concentrations. AEDT is not intended for PSD, SIP, or other regulatory air quality analyses of point or mobile sources at or peripheral to airport property that are unrelated to airport operations. The latest version of AEDT may be obtained from the FAA at: <https://aedt.faa.gov>.

## 7.0 General Modeling Considerations

### 7.1 Discussion

a. This section contains recommendations concerning a number of different issues not explicitly covered in other sections of the *Guideline*. The topics covered here are not specific to any one program or modeling area, but are common to dispersion modeling analyses for criteria pollutants.

### 7.2 Recommendations

#### 7.2.1 All Sources

##### 7.2.1.1 Dispersion Coefficients

a. For any dispersion modeling exercise, the urban or rural determination of a source is critical in determining the boundary layer characteristics that affect the model's prediction of downwind concentrations. Historically, steady-state Gaussian plume models used in most applications have employed dispersion coefficients based on Pasquill-Gifford<sup>72</sup> in rural areas and McElroy-Pooler<sup>73</sup> in urban areas. These coefficients are still incorporated in the BLP and OCD models. However, the AERMOD model incorporates a more up-to-date characterization of the atmospheric boundary layer using continuous functions of parameterized horizontal and vertical turbulence based on Monin-Obukhov similarity (scaling) relationships.<sup>44</sup> Another key feature of AERMOD's formulation is the option to use directly observed variables of the boundary layer to parameterize dispersion.<sup>44, 45</sup>

b. The selection of rural or urban dispersion coefficients in a specific application should follow one of the procedures suggested by Irwin<sup>74</sup> to determine whether the character of an area is primarily urban or rural (of the two methods, the land use procedure is considered more definitive.):

i. Land Use Procedure: (1) Classify the land use within the total area,  $A_o$ , circumscribed by a 3 km radius circle about the source using the meteorological land use typing scheme proposed by Auer;<sup>75</sup> (2) if land use types I1, I2, C1, R2, and R3 account for 50 percent or more of  $A_o$ , use urban dispersion coefficients; otherwise, use appropriate rural dispersion coefficients.

ii. Population Density Procedure: (1) Compute the average population density,  $\bar{p}$  per square kilometer with  $A_o$  as defined above; (2) If  $\bar{p}$  is greater than 750 people per square kilometer, use urban dispersion coefficients; otherwise use appropriate rural dispersion coefficients.

c. Population density should be used with caution and generally not be applied to highly industrialized areas where the population density may be low and, thus, a rural classification would be indicated. However, the area is likely to be sufficiently built-up so that the urban land use criteria would be satisfied. Therefore, in this case, the classification should be "urban" and urban dispersion parameters should be used.

d. For applications of AERMOD in urban areas, under either the Land Use Procedure or the Population Density Procedure, the user needs to estimate the population of the urban area affecting the modeling domain because the urban influence in AERMOD is scaled

based on a user-specified population. For non-population oriented urban areas, or areas influenced by both population and industrial activity, the user will need to estimate an equivalent population to adequately account for the combined effects of industrialized areas and populated areas within the modeling domain. Selection of the appropriate population for these applications should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)) and the latest version of the AERMOD Implementation Guide.<sup>76</sup>

e. It should be noted that AERMOD allows for modeling rural and urban sources in a single model run. For analyses of whole urban complexes, the entire area should be modeled as an urban region if most of the sources are located in areas classified as urban. For tall stacks located within or adjacent to small or moderate sized urban areas, the stack height or effective plume height may extend above the urban boundary layer and, therefore, may be more appropriately modeled using rural coefficients. Model users should consult with the appropriate reviewing authority (paragraph 3.0(b)) and the latest version of the AERMOD Implementation Guide<sup>76</sup> when evaluating this situation.

f. Buoyancy-induced dispersion (BID), as identified by Pasquill,<sup>77</sup> is included in the preferred models and should be used where buoyant sources (*e.g.*, those involving fuel combustion) are involved.

##### 7.2.1.2 Complex Winds

a. *Inhomogeneous local winds*. In many parts of the United States, the ground is neither flat nor is the ground cover (or land use) uniform. These geographical variations can generate local winds and circulations, and modify the prevailing ambient winds and circulations. Typically, geographic effects are more apparent when the ambient winds are light or calm, as stronger synoptic or mesoscale winds can modify, or even eliminate the weak geographic circulations.<sup>78</sup> In general, these geographically induced wind circulation effects are named after the source location of the winds, *e.g.*, lake and sea breezes, and mountain and valley winds. In very rugged hilly or mountainous terrain, along coastlines, or near large land use variations, the characteristics of the winds are a balance of various forces, such that the assumptions of steady-state straight-line transport both in time and space are inappropriate. In such cases, a model should be chosen to fully treat the time and space variations of meteorology effects on transport and dispersion. The setup and application of such a model should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)) consistent with limitations of paragraph 3.2.2(e). The meteorological input data requirements for developing the time and space varying three-dimensional winds and dispersion meteorology for these situations are discussed in paragraph 8.4.1.2(c). Examples of inhomogeneous winds include, but are not limited to, situations described in the following paragraphs:

i. *Inversion breakup fumigation*. Inversion breakup fumigation occurs when a plume (or multiple plumes) is emitted into a stable

layer of air and that layer is subsequently mixed to the ground through convective transfer of heat from the surface or because of advection to less stable surroundings. Fumigation may cause excessively high concentrations, but is usually rather short-lived at a given receptor. There are no recommended refined techniques to model this phenomenon. There are, however, screening procedures<sup>40</sup> that may be used to approximate the concentrations. Considerable care should be exercised in using the results obtained from the screening techniques.

ii. *Shoreline fumigation*. Fumigation can be an important phenomenon on and near the shoreline of bodies of water. This can affect both individual plumes and area-wide emissions. When fumigation conditions are expected to occur from a source or sources with tall stacks located on or just inland of a shoreline, this should be addressed in the air quality modeling analysis. The EPA has evaluated several coastal fumigation models, and the evaluation results of these models are available for their possible application on a case-by-case basis when air quality estimates under shoreline fumigation conditions are needed.<sup>79</sup> Selection of the appropriate model for applications where shoreline fumigation is of concern should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

iii. *Stagnation*. Stagnation conditions are characterized by calm or very low wind speeds, and variable wind directions. These stagnant meteorological conditions may persist for several hours to several days. During stagnation conditions, the dispersion of air pollutants, especially those from low-level emissions sources, tends to be minimized, potentially leading to relatively high ground-level concentrations. If point sources are of interest, users should note the guidance provided in paragraph (a) of this subsection. Selection of the appropriate model for applications where stagnation is of concern should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

##### 7.2.1.3 Gravitational Settling and Deposition

a. Gravitational settling and deposition may be directly included in a model if either is a significant factor. When particulate matter sources can be quantified and settling and dry deposition are problems, use professional judgment along with coordination with the appropriate reviewing authority (paragraph 3.0(b)). AERMOD contains algorithms for dry and wet deposition of gases and particles.<sup>80</sup> For other Gaussian plume models, an "infinite half-life" may be used for estimates of particle concentrations when only exponential decay terms are used for treating settling and deposition. Lagrangian models have varying degrees of complexity for dealing with settling and deposition and the selection of a parameterization for such should be included in the approval process for selecting a Lagrangian model. Eulerian grid models tend to have explicit parameterizations for gravitational settling and deposition as well as wet deposition parameters already included as part of the chemistry scheme.

## 7.2.2 Stationary Sources

### 7.2.2.1 Good Engineering Practice Stack Height

a. The use of stack height credit in excess of Good Engineering Practice (GEP) stack height or credit resulting from any other dispersion technique is prohibited in the development of emissions limits by 40 CFR 51.118 and 40 CFR 51.164. The definition of GEP stack height and dispersion technique are contained in 40 CFR 51.100. Methods and procedures for making the appropriate stack height calculations, determining stack height credits and an example of applying those techniques are found in several references,<sup>81 82 83 84</sup> that provide a great deal of additional information for evaluating and describing building cavity and wake effects.

b. If stacks for new or existing major sources are found to be less than the height defined by the EPA's refined formula for determining GEP height, then air quality impacts associated with cavity and wake effects due to the nearby building structures should be determined. The EPA refined formula height is defined as  $H + 1.5L$ .<sup>83</sup> Since the definition of GEP stack height defines excessive concentrations as a maximum ground-level concentration due in whole or in part to downwash of at least 40 percent in excess of the maximum concentration without downwash, the potential air quality impacts associated with cavity and wake effects should also be considered for stacks that equal or exceed the EPA formula height for GEP. The AERSCREEN model can be used to obtain screening estimates of potential downwash influences, based on the PRIME downwash algorithm incorporated in the AERMOD model. If more refined concentration estimates are required, AERMOD should be used (section 4.2.2).

### 7.2.2.2 Plume Rise

a. The plume rise methods of Briggs<sup>85 86</sup> are incorporated in many of the preferred models and are recommended for use in many modeling applications. In AERMOD,<sup>44 45</sup> for the stable boundary layer, plume rise is estimated using an iterative approach, similar to that in the CTDMPLUS model. In the convective boundary layer, plume rise is superposed on the displacements by random convective velocities.<sup>87</sup> In AERMOD, plume rise is computed using the methods of Briggs, except in cases involving building downwash, in which a numerical solution of the mass, energy, and momentum conservation laws is performed.<sup>88</sup> No explicit provisions in these models are made for multistack plume rise enhancement or the handling of such special plumes as flares.

b. Gradual plume rise is generally recommended where its use is appropriate: (1) In AERMOD; (2) in complex terrain screening procedures to determine close-in impacts; and (3) when calculating the effects of building wakes. The building wake algorithm in AERMOD incorporates and exercises the thermodynamically based gradual plume rise calculations as described in paragraph (a) of this subsection. If the building wake is calculated to affect the plume for any hour, gradual plume rise is also used in downwind dispersion

calculations to the distance of final plume rise, after which final plume rise is used. Plumes captured by the near wake are re-emitted to the far wake as a ground-level volume source.

c. Stack tip downwash generally occurs with poorly constructed stacks and when the ratio of the stack exit velocity to wind speed is small. An algorithm developed by Briggs<sup>86</sup> is the recommended technique for this situation and is used in preferred models for point sources.

d. On a case-by-case basis, refinements to the preferred model may be considered for plume rise and downwash effects and shall occur in agreement with the appropriate reviewing authority (paragraph 3.0(b)) and approval by the EPA Regional Office based on the requirements of section 3.2.2.

### 7.2.3 Mobile Sources

a. Emissions of primary pollutants from mobile sources can be modeled with an appropriate model identified in section 4.2. Screening of mobile sources can be accomplished by using screening meteorology, *e.g.*, worst-case meteorological conditions. Maximum hourly concentrations computed from screening modeling can be converted to longer averaging periods using the scaling ratios specified in the AERSCREEN User's Guide.<sup>37</sup>

b. Mobile sources can be modeled in AERMOD as either line (*i.e.*, elongated area) sources or as a series of volume sources. However, since mobile source modeling usually includes an analysis of very near-source impacts (*e.g.*, hot-spot modeling, which can include receptors within 5–10 meters (m) of the roadway), the results can be highly sensitive to the characterization of the mobile emissions. Important characteristics for both line/area and volume sources include the plume release height, source width, and initial dispersion characteristics, and should also take into account the impact of traffic-induced turbulence that can cause roadway sources to have larger initial dimensions than might normally be used for representing line sources.

c. The EPA's quantitative PM hot-spot guidance<sup>61</sup> and Haul Road Workgroup Final Report<sup>63</sup> provide guidance on the appropriate characterization of mobile sources as a function of the roadway and vehicle characteristics. The EPA's quantitative PM hot-spot guidance includes important considerations and should be consulted when modeling roadway links. Area, line or volume sources may be used for modeling mobile sources. However, experience in the field has shown that area sources may be easier to characterize correctly compared to volume sources. If volume sources are used, it is particularly important to ensure that roadway emissions are appropriately spaced when using volume source so that the emissions field is uniform across the roadway. Additionally, receptor placement is particularly important for volume sources that have "exclusion zones" where concentrations are not calculated for receptors located "within" the volume sources, *i.e.*, less than 2.15 times the initial lateral dispersion coefficient from the center of the volume.<sup>61</sup> Placing receptors in these

"exclusion zones" will result in underestimates of roadway impacts.

## 8.0 Model Input Data

a. Databases and related procedures for estimating input parameters are an integral part of the modeling process. The most appropriate input data available should always be selected for use in modeling analyses. Modeled concentrations can vary widely depending on the source data or meteorological data used. This section attempts to minimize the uncertainty associated with database selection and use by identifying requirements for input data used in modeling. More specific data requirements and the format required for the individual models are described in detail in the user's guide and/or associated documentation for each model.

### 8.1 Modeling Domain

#### 8.1.1 Discussion

a. The modeling domain is the geographic area for which the required air quality analyses for the NAAQS and PSD increments are conducted.

#### 8.1.2 Requirements

a. For a NAAQS or PSD increments assessment, the modeling domain or project's impact area shall include all locations where the emissions of a pollutant from the new or modifying source(s) may cause a significant ambient impact. This impact area is defined as an area with a radius extending from the new or modifying source to: (1) The most distant location where air quality modeling predicts a significant ambient impact will occur, or (2) the nominal 50 km distance considered applicable for Gaussian dispersion models, whichever is less. The required air quality analysis shall be carried out within this geographical area with characterization of source impacts, nearby source impacts, and background concentrations, as recommended later in this section.

b. For SIP attainment demonstrations for ozone and PM<sub>2.5</sub>, or regional haze reasonable progress goal analyses, the modeling domain is determined by the nature of the problem being modeled and the spatial scale of the emissions that impact the nonattainment or Class I area(s). The modeling domain shall be designed so that all major upwind source areas that influence the downwind nonattainment area are included in addition to all monitor locations that are currently or recently violating the NAAQS or close to violating the NAAQS in the nonattainment area. Similarly, all Class I areas to be evaluated in a regional haze modeling application shall be included and sufficiently distant from the edge of the modeling domain. Guidance on the determination of the appropriate modeling domain for photochemical grid models in demonstrating attainment of these air quality goals is available.<sup>60</sup> Users should consult the latest version of this guidance for the most current modeling guidance and the appropriate reviewing authority (paragraph 3.0(b)) for any application specific guidance that is beyond the scope of this section.

## 8.2 Source Data

### 8.2.1 Discussion

a. Sources of pollutants can be classified as point, line, area, and volume sources. Point sources are defined in terms of size and may vary between regulatory programs. The line sources most frequently considered are roadways and streets along which there are well-defined movements of motor vehicles. They may also be lines of roof vents or stacks, such as in aluminum refineries. Area and volume sources are often collections of a multitude of minor sources with individually small emissions that are impractical to consider as separate point or line sources. Large area sources are typically treated as a grid network of square areas, with pollutant emissions distributed uniformly within each grid square. Generally, input data requirements for air quality models necessitate the use of metric units. As necessary, any English units common to engineering applications should be appropriately converted to metric.

b. For point sources, there are many source characteristics and operating conditions that may be needed to appropriately model the facility. For example, the plant layout (e.g., location of stacks and buildings), stack parameters (e.g., height and diameter), boiler size and type, potential operating conditions, and pollution control equipment parameters. Such details are required inputs to air quality models and are needed to determine maximum potential impacts.

c. Modeling mobile emissions from streets and highways requires data on the road layout, including the width of each traveled lane, the number of lanes, and the width of the median strip. Additionally, traffic patterns should be taken into account (e.g., daily cycles of rush hour, differences in weekday and weekend traffic volumes, and changes in the distribution of heavy-duty trucks and light-duty passenger vehicles), as these patterns will affect the types and amounts of pollutant emissions allocated to each lane and the height of emissions.

d. Emission factors can be determined through source-specific testing and measurements (e.g., stack test data) from existing sources or provided from a manufacturing association or vendor. Additionally, emissions factors for a variety of source types are compiled in an EPA publication commonly known as AP-42.<sup>89</sup> AP-42 also provides an indication of the quality and amount of data on which many of the factors are based. Other information concerning emissions is available in EPA publications relating to specific source categories. The appropriate reviewing authority (paragraph 3.0(b)) should be consulted to determine appropriate source definitions and for guidance concerning the

determination of emissions from and techniques for modeling the various source types.

### 8.2.2 Requirements

a. For SIP attainment demonstrations for the purpose of projecting future year NAAQS attainment for ozone, PM<sub>2.5</sub>, and regional haze reasonable progress goal analyses, emissions which reflect actual emissions during the base modeling year time period should be input to models for base year modeling. Emissions projections to future years should account for key variables such as growth due to increased or decreased activity, expected emissions controls due to regulations, settlement agreements or consent decrees, fuel switches, and any other relevant information. Guidance on emissions estimation techniques (including future year projections) for SIP attainment demonstrations is available.<sup>60 90</sup>

b. For the purpose of SIP revisions for stationary point sources, the regulatory modeling of inert pollutants shall use the emissions input data shown in Table 8-1 for short-term and long-term NAAQS. To demonstrate compliance and/or establish the appropriate SIP emissions limits, Table 8-1 generally provides for the use of "allowable" emissions in the regulatory dispersion modeling of the stationary point source(s) of interest. In such modeling, these source(s) should be modeled sequentially with these loads for every hour of the year. As part of a cumulative impact analysis, Table 8-1 allows for the model user to account for actual operations in developing the emissions inputs for dispersion modeling of nearby sources, while other sources are best represented by air quality monitoring data. Consultation with the appropriate reviewing authority (paragraph 3.0(b)) is advisable on the establishment of the appropriate emissions inputs for regulatory modeling applications with respect to SIP revisions for stationary point sources.

c. For the purposes of demonstrating NAAQS compliance in a PSD assessment, the regulatory modeling of inert pollutants shall use the emissions input data shown in Table 8-2 for short and long-term NAAQS. The new or modifying stationary point source shall be modeled with "allowable" emissions in the regulatory dispersion modeling. As part of a cumulative impact analysis, Table 8-2 allows for the model user to account for actual operations in developing the emissions inputs for dispersion modeling of nearby sources, while other sources are best represented by air quality monitoring data. For purposes of situations involving emissions trading, refer to current EPA policy and guidance to establish input data. Consultation with the appropriate reviewing authority (paragraph 3.0(b)) is advisable on

the establishment of the appropriate emissions inputs for regulatory modeling applications with respect to PSD assessments for a proposed new or modifying source.

d. For stationary source applications, changes in operating conditions that affect the physical emission parameters (e.g., release height, initial plume volume, and exit velocity) shall be considered to ensure that maximum potential impacts are appropriately determined in the assessment. For example, the load or operating condition for point sources that causes maximum ground-level concentrations shall be established. As a minimum, the source should be modeled using the design capacity (100 percent load). If a source operates at greater than design capacity for periods that could result in violations of the NAAQS or PSD increments, this load should be modeled. Where the source operates at substantially less than design capacity, and the changes in the stack parameters associated with the operating conditions could lead to higher ground level concentrations, loads such as 50 percent and 75 percent of capacity should also be modeled. Malfunctions which may result in excess emissions are not considered to be a normal operating condition. They generally should not be considered in determining allowable emissions. However, if the excess emissions are the result of poor maintenance, careless operation, or other preventable conditions, it may be necessary to consider them in determining source impact. A range of operating conditions should be considered in screening analyses. The load causing the highest concentration, in addition to the design load, should be included in refined modeling.

e. Emissions from mobile sources also have physical and temporal characteristics that should be appropriately accounted. For example, an appropriate emissions model shall be used to determine emissions profiles. Such emissions should include speciation specific for the vehicle types used on the roadway (e.g., light duty and heavy duty trucks), and subsequent parameterizations of the physical emissions characteristics (e.g., release height) should reflect those emissions sources. For long-term standards, annual average emissions may be appropriate, but for short-term standards, discrete temporal representation of emissions should be used (e.g., variations in weekday and weekend traffic or the diurnal rush-hour profile typical of many cities). Detailed information and data requirements for modeling mobile sources of pollution are provided in the user's manuals for each of the models applicable to mobile sources.<sup>61 63</sup>



**Table 8-1. - Point Source Model Emission Inputs for SIP Revisions of Inert Pollutants<sup>1</sup>**

Averaging time	Emissions limit (lb/MMBtu) <sup>2</sup>	X	Operating level (MMBtu/hr) <sup>2</sup>	X	Operating factor (e.g., hr/yr, hr/day)
<b>Stationary Point Source(s) Subject to SIP Emissions Limit(s) Evaluation for Compliance with Ambient Standards</b> (Including Areawide Demonstrations)					
Annual & quarterly .....	Maximum allowable emission limit or federally enforceable permit limit.		Actual or design capacity (whichever is greater), or federally enforceable permit condition.		Actual operating factor averaged over the most recent 2 years. <sup>3</sup>
Short term (≤ 24 hours) .....	Maximum allowable emission limit or federally enforceable permit limit.		Actual or design capacity (whichever is greater), or federally enforceable permit condition. <sup>4</sup>		Continuous operation, i.e., all hours of each time period under consideration (for all hours of the meteorological database). <sup>5</sup>
<b>Nearby Source(s)<sup>6</sup></b>					
Annual & quarterly .....	Maximum allowable emission limit or federally enforceable permit limit. <sup>6</sup>		Annual level when actually operating, averaged over the most recent 2 years. <sup>3</sup>		Actual operating factor averaged over the most recent 2 years. <sup>3,8</sup>
Short term (≤ 24 hours) .....	Maximum allowable emission limit or federally enforceable permit limit. <sup>6</sup>		Temporally representative level when actually operating, reflective of the most recent 2 years. <sup>3,7</sup>		Continuous operation, i.e., all hours of each time period under consideration (for all hours of the meteorological database). <sup>5</sup>
<b>Other Source(s)<sup>6,9</sup></b>					

The ambient impacts from Non-nearby or Other Sources (e.g., natural sources, minor sources and distant major sources, and unidentified sources) can be represented by air quality monitoring data unless adequate data do not exist.

1. For purposes of emissions trading, NSR, or PSD, other model input criteria may apply. See Section 8.2 for more information regarding attainment demonstrations of primary PM<sub>2.5</sub>.
2. Terminology applicable to fuel burning sources; analogous terminology (e.g., lb/throughput) may be used for other types of sources.
3. Unless it is determined that this period is not representative.
4. Operating levels such as 50 percent and 75 percent of capacity should also be modeled to determine the load causing the highest concentration.
5. If operation does not occur for all hours of the time period of consideration (e.g., 3 or 24-hours) and the source operation is constrained by a federally enforceable permit condition, an appropriate adjustment to the modeled emission rate may be made (e.g., if operation is only 8 a.m. to 4 p.m. each day, only these hours will be modeled with emissions from the source. Modeled emissions should not be averaged across non-operating time periods.)
6. See Section 8.3.3.
7. Temporally representative operating level could be based on Continuous Emissions Monitoring (CEM) data or other information and should be determined through consultation with the appropriate reviewing authority (Paragraph 3.0(b)).
8. For those permitted sources not in operation or that have not established an appropriate factor, continuous operation (i.e., 8760) should be used.
9. See Section 8.3.2.

**Table 8-2. - Point Source Model Emission Inputs for NAAQS Compliance in PSD Demonstrations**

Averaging time	Emissions limit (lb/MMBtu) <sup>1</sup>	X	Operating level (MMBtu/hr) <sup>2</sup>	X	Operating factor (e.g., hr/yr, hr/day)
<b>Proposed Major New or Modified Source</b>					
Annual & quarterly .....	Maximum allowable emission limit or federally enforceable permit limit.		Design capacity or federally enforceable permit condition.		Continuous operation (i.e., 8760 hours). <sup>2</sup>
Short term (≤ 24 hours) .....	Maximum allowable emission limit or federally enforceable permit limit.		Design capacity or federally enforceable permit condition. <sup>3</sup>		Continuous operation, i.e., all hours of each time period under consideration (for all hours of the meteorological database). <sup>2</sup>
<b>Nearby Source(s)<sup>4,5</sup></b>					
Annual & quarterly .....	Maximum allowable emission limit or federally enforceable permit limit. <sup>5</sup>		Annual level when actually operating, averaged over the most recent 2 years. <sup>6</sup>		Actual operating factor averaged over the most recent 2 years. <sup>6,8</sup>
Short term (≤ 24 hours) .....	Maximum allowable emission limit or federally enforceable permit limit. <sup>5</sup>		Temporally representative level when actually operating, reflective of the most recent 2 years. <sup>6,7</sup>		Continuous operation, i.e., all hours of each time period under consideration (for all hours of the meteorological database). <sup>2</sup>
<b>Other Source(s)<sup>5,9</sup></b>					

The ambient impacts from Non-nearby or Other Sources (e.g., natural sources, minor sources and distant major sources, and unidentified sources) can be represented by air quality monitoring data unless adequate data do not exist.

1. Terminology applicable to fuel burning sources; analogous terminology (e.g., lb/throughput) may be used for other types of sources.
2. If operation does not occur for all hours of the time period of consideration (e.g., 3 or 24-hours) and the source operation is constrained by a federally enforceable permit condition, an appropriate adjustment to the modeled emission rate may be made (e.g., if operation is only 8 a.m. to 4 p.m. each day, only these hours will be modeled with emissions from the source. Modeled emissions should not be averaged across non-operating time periods.
3. Operating levels such as 50 percent and 75 percent of capacity should also be modeled to determine the load causing the highest concentration.
4. Includes existing facility to which modification is proposed if the emissions from the existing facility will not be affected by the modification. Otherwise use the same parameters as for major modification.
5. See Section 8.3.3.
6. Unless it is determined that this period is not representative.
7. Temporally representative operating level could be based on Continuous Emissions Monitoring (CEM) data or other information and should be determined through consultation with the appropriate reviewing authority (Paragraph 3.0(b)).
8. For those permitted sources not in operation or that have not established an appropriate factor, continuous operation (i.e., 8760) should be used.
9. See Section 8.3.2.

**8.3 Background Concentrations**

**8.3.1 Discussion**

a. Background concentrations are essential in constructing the design concentration, or total air quality concentration, as part of a cumulative impact analysis for NAAQS and PSD increments (section 9.2.3). Background air quality should not include the ambient impacts of the project source under consideration. Instead, it should include:

i. Nearby sources: These are individual sources located in the vicinity of the source(s) under consideration for emissions limits that are not adequately represented by ambient monitoring data. Typically, sources that cause a significant concentration gradient in the vicinity of the source(s) under consideration for emissions limits are not adequately represented by background ambient monitoring. The ambient

contributions from these nearby sources are thereby accounted for by explicitly modeling their emissions (section 8.2).

ii. Other sources: That portion of the background attributable to natural sources, other unidentified sources in the vicinity of the project, and regional transport contributions from more distant sources (domestic and international). The ambient contributions from these sources are typically accounted for through use of ambient monitoring data or, in some cases, regional-scale photochemical grid modeling results.

b. The monitoring network used for developing background concentrations is expected to conform to the same quality assurance and other requirements as those networks established for PSD purposes.<sup>91</sup> Accordingly, the air quality monitoring data should be of sufficient completeness and follow appropriate data validation

procedures. These data should be adequately representative of the area to inform calculation of the design concentration for comparison to the applicable NAAQS (section 9.2.2).

c. For photochemical grid modeling conducted in SIP attainment demonstrations for ozone, PM<sub>2.5</sub> and regional haze, the emissions from nearby and other sources are included as model inputs and fully accounted for in the modeling application and predicted concentrations. The concept of adding individual components to develop a design concentration, therefore, do not apply in these SIP applications. However, such modeling results may then be appropriate for consideration in characterizing background concentrations for other regulatory applications. Also, as noted in section 5, this modeling approach does provide for an appropriate atmospheric environment to

assess single-source impacts for ozone and secondary PM<sub>2.5</sub>.

d. For NAAQS assessments and SIP attainment demonstrations for inert pollutants, the development of the appropriate background concentration for a cumulative impact analysis involves proper accounting of each contribution to the design concentration and will depend upon whether the project area's situation consists of either an isolated single source(s) or a multitude of sources. For PSD increment assessments, all impacts after the appropriate baseline dates (*i.e.*, trigger date, major source baseline date, and minor source baseline date) from all increment-consuming and increment-expanding sources should be considered in the design concentration (section 9.2.2).

### 8.3.2 Recommendations for Isolated Single Sources

a. In areas with an isolated source(s), determining the appropriate background concentration should focus on characterization of contributions from all other sources through adequately representative ambient monitoring data.

b. The EPA recommends use of the most recent quality assured air quality monitoring data collected in the vicinity of the source to determine the background concentration for the averaging times of concern. In most cases, the EPA recommends using data from the monitor closest to and upwind of the project area. If several monitors are available, preference should be given to the monitor with characteristics that are most similar to the project area. If there are no monitors located in the vicinity of the new or modifying source, a "regional site" may be used to determine background concentrations. A regional site is one that is located away from the area of interest but is impacted by similar or adequately representative sources.

c. Many of the challenges related to cumulative impact analyses arise in the context of defining the appropriate metric to characterize background concentrations from ambient monitoring data and determining the appropriate method for combining this monitor-based background contribution to the modeled impact of the project and other nearby sources. For many cases, the best starting point would be use of the current design value for the applicable NAAQS as a uniform monitored background contribution across the project area. However, there are cases in which the current design value may not be appropriate. Such cases include but are not limited to:

i. For situations involving a modifying source where the existing facility is determined to impact the ambient monitor, the background concentration at each monitor can be determined by excluding values when the source in question is impacting the monitor. In such cases, monitoring sites inside a 90° sector downwind of the source may be used to determine the area of impact.

ii. There may be other circumstances which would necessitate modifications to the ambient data record. Such cases could include removal of data from specific days or hours when a monitor is being impacted by activities that are not typical or not expected

to occur again in the future (*e.g.*, construction, roadway repairs, forest fires, or unusual agricultural activities). There may also be cases where it may be appropriate to scale (multiplying the monitored concentrations with a scaling factor) or adjust (adding or subtracting a constant value the monitored concentrations) data from specific days or hours. Such adjustments would make the monitored background concentrations more temporally and/or spatially representative of the area around the new or modifying source for the purposes of the regulatory assessment.

iii. For short-term standards, the diurnal or seasonal patterns of the air quality monitoring data may differ significantly from the patterns associated with the modeled concentrations. When this occurs, it may be appropriate to pair the air quality monitoring data in a temporal manner that reflects these patterns (*e.g.*, pairing by season and/or hour of day).<sup>92</sup>

iv. For situations where monitored air quality concentrations vary across the modeling domain, it may be appropriate to consider air quality monitoring data from multiple monitors within the project area.

d. Determination of the appropriate background concentrations should be consistent with appropriate EPA modeling guidance<sup>59,60</sup> and justified in the modeling protocol that is vetted with the appropriate reviewing authority (paragraph 3.0(b)).

e. Considering the spatial and temporal variability throughout a typical modeling domain on an hourly basis and the complexities and limitations of hourly observations from the ambient monitoring network, the EPA does not recommend hourly or daily pairing of monitored background and modeled concentrations except in rare cases of relatively isolated sources where the available monitor can be shown to be representative of the ambient concentration levels in the areas of maximum impact from the proposed new source. The implicit assumption underlying hourly pairing is that the background monitored levels for each hour are spatially uniform and that the monitored values are fully representative of background levels at each receptor for each hour. Such an assumption clearly ignores the many factors that contribute to the temporal and spatial variability of ambient concentrations across a typical modeling domain on an hourly basis. In most cases, the seasonal (or quarterly) pairing of monitored and modeled concentrations should sufficiently address situations to which the impacts from modeled emissions are not temporally correlated with background monitored levels.

f. In those cases where adequately representative monitoring data to characterize background concentrations are not available, it may be appropriate to use results from a regional-scale photochemical grid model, or other representative model application, as background concentrations consistent with the considerations discussed above and in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

### 8.3.3 Recommendations for Multi-Source Areas

a. In multi-source areas, determining the appropriate background concentration involves: (1) Identification and characterization of contributions from nearby sources through explicit modeling, and (2) characterization of contributions from other sources through adequately representative ambient monitoring data. A key point here is the interconnectedness of each component in that the question of which nearby sources to include in the cumulative modeling is inextricably linked to the question of what the ambient monitoring data represents within the project area.

b. *Nearby sources:* All sources in the vicinity of the source(s) under consideration for emissions limits that are not adequately represented by ambient monitoring data should be explicitly modeled. Since an ambient monitor is limited to characterizing air quality at a fixed location, sources that cause a significant concentration gradient in the vicinity of the source(s) under consideration for emissions limits are not likely to be adequately characterized by the monitored data due to the high degree of variability of the source's impact.

i. The pattern of concentration gradients can vary significantly based on the averaging period being assessed. In general, concentration gradients will be smaller and more spatially uniform for annual averages than for short-term averages, especially for hourly averages. The spatial distribution of annual impacts around a source will often have a single peak downwind of the source based on the prevailing wind direction, except in cases where terrain or other geographic effects are important. By contrast, the spatial distribution of peak short-term impacts will typically show several localized concentration peaks with more significant gradient.

ii. Concentration gradients associated with a particular source will generally be largest between that source's location and the distance to the maximum ground-level concentrations from that source. Beyond the maximum impact distance, concentration gradients will generally be much smaller and more spatially uniform. Thus, the magnitude of a concentration gradient will be greatest in the proximity of the source and will generally not be significant at distances greater than 10 times the height of the stack(s) at that source without consideration of terrain influences.

iii. The number of nearby sources to be explicitly modeled in the air quality analysis is expected to be few except in unusual situations. In most cases, the few nearby sources will be located within the first 10 to 20 km from the source(s) under consideration. Owing to both the uniqueness of each modeling situation and the large number of variables involved in identifying nearby sources, no attempt is made here to comprehensively define a "significant concentration gradient." Rather, identification of nearby sources calls for the exercise of professional judgment by the appropriate reviewing authority (paragraph 3.0(b)). This guidance is not intended to alter the exercise of that judgment or to

comprehensively prescribe which sources should be included as nearby sources.

c. For cumulative impact analyses of short-term and annual ambient standards, the nearby sources as well as the project source(s) must be evaluated using an appropriate appendix A model or approved alternative model with the emission input data shown in Table 8-1 or 8-2.

i. When modeling a nearby source that does not have a permit and the emissions limits contained in the SIP for a particular source category is greater than the emissions possible given the source's maximum physical capacity to emit, the "maximum allowable emissions limit" for such a nearby source may be calculated as the emissions rate representative of the nearby source's maximum physical capacity to emit, considering its design specifications and allowable fuels and process materials. However, the burden is on the permit applicant to sufficiently document what the maximum physical capacity to emit is for such a nearby source.

ii. It is appropriate to model nearby sources only during those times when they, by their nature, operate at the same time as the primary source(s) or could have impact on the averaging period of concern. Accordingly, it is not necessary to model impacts of a nearby source that does not, by its nature, operate at the same time as the primary source or could have impact on the averaging period of concern, regardless of an identified significant concentration gradient from the nearby source. The burden is on the permit applicant to adequately justify the exclusion of nearby sources to the satisfaction of the appropriate reviewing authority (paragraph 3.0(b)). The following examples illustrate two cases in which a nearby source may be shown not to operate at the same time as the primary source(s) being modeled: (1) Seasonal sources (only used during certain seasons of the year). Such sources would not be modeled as nearby sources during times in which they do not operate; and (2) Emergency backup generators, to the extent that they do not operate simultaneously with the sources that they back up. Such emergency equipment would not be modeled as nearby sources.

d. *Other sources.* That portion of the background attributable to all other sources (e.g., natural sources, minor and distant major sources) should be accounted for through use of ambient monitoring data and determined by the procedures found in section 8.3.2 in keeping with eliminating or reducing the source-oriented impacts from nearby sources to avoid potential double-counting of modeled and monitored contributions.

#### 8.4 Meteorological Input Data

##### 8.4.1 Discussion

a. This subsection covers meteorological input data for use in dispersion modeling for regulatory applications and is separate from recommendations made for photochemical grid modeling. Recommendations for meteorological data for photochemical grid modeling applications are outlined in the latest version of EPA's *Modeling Guidance for Demonstrating Attainment of Air Quality*

*Goals for Ozone, PM<sub>2.5</sub>, and Regional Haze*.<sup>60</sup> In cases where Lagrangian models are applied for regulatory purposes, appropriate meteorological inputs should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

b. The meteorological data used as input to a dispersion model should be selected on the basis of spatial and climatological (temporal) representativeness as well as the ability of the individual parameters selected to characterize the transport and dispersion conditions in the area of concern. The representativeness of the measured data is dependent on numerous factors including, but not limited to: (1) The proximity of the meteorological monitoring site to the area under consideration; (2) the complexity of the terrain; (3) the exposure of the meteorological monitoring site; and (4) the period of time during which data are collected. The spatial representativeness of the data can be adversely affected by large distances between the source and receptors of interest and the complex topographic characteristics of the area. Temporal representativeness is a function of the year-to-year variations in weather conditions. Where appropriate, data representativeness should be viewed in terms of the appropriateness of the data for constructing realistic boundary layer profiles and, where applicable, three-dimensional meteorological fields, as described in paragraphs (c) and (d) of this subsection.

c. The meteorological data should be adequately representative and may be site-specific data, data from a nearby National Weather Service (NWS) or comparable station, or prognostic meteorological data. The implementation of NWS Automated Surface Observing Stations (ASOS) in the early 1990's should not preclude the use of NWS ASOS data if such a station is determined to be representative of the modeled area.<sup>93</sup>

d. Model input data are normally obtained either from the NWS or as part of a site-specific measurement program. State climatology offices, local universities, FAA, military stations, industry, and pollution control agencies may also be sources of such data. In specific cases, prognostic meteorological data may be appropriate for use and obtained from similar sources. Some recommendations and requirements for the use of each type of data are included in this subsection.

##### 8.4.2 Recommendations and Requirements

a. AERMET<sup>94</sup> shall be used to preprocess all meteorological data, be it observed or prognostic, for use with AERMOD in regulatory applications. The AERMINUTE<sup>95</sup> processor, in most cases, should be used to process 1-minute ASOS wind data for input to AERMET when processing NWS ASOS sites in AERMET. When processing prognostic meteorological data for AERMOD, the Mesoscale Model Interface Program (MMIF)<sup>103</sup> should be used to process data for input to AERMET. Other methods of processing prognostic meteorological data for input to AERMET should be approved by the appropriate reviewing authority. Additionally, the following meteorological preprocessors are recommended by the EPA:

PCRAMMET,<sup>96</sup> MPRM,<sup>97</sup> and METPRO.<sup>98</sup> PCRAMMET is the recommended meteorological data preprocessor for use in applications of OCD employing hourly NWS data. MPRM is the recommended meteorological data preprocessor for applications of OCD employing site-specific meteorological data. METPRO is the recommended meteorological data preprocessor for use with CTDMPPLUS.<sup>99</sup>

b. Regulatory application of AERMOD necessitates careful consideration of the meteorological data for input to AERMET. Data representativeness, in the case of AERMOD, means utilizing data of an appropriate type for constructing realistic boundary layer profiles. Of particular importance is the requirement that all meteorological data used as input to AERMOD should be adequately representative of the transport and dispersion within the analysis domain. Where surface conditions vary significantly over the analysis domain, the emphasis in assessing representativeness should be given to adequate characterization of transport and dispersion between the source(s) of concern and areas where maximum design concentrations are anticipated to occur. The EPA recommends that the surface characteristics input to AERMET should be representative of the land cover in the vicinity of the meteorological data, *i.e.*, the location of the meteorological tower for measured data or the representative grid cell for prognostic data. Therefore, the model user should apply the latest version AERSURFACE,<sup>100 101</sup> where applicable, for determining surface characteristics when processing measured meteorological data through AERMET. In areas where it is not possible to use AERSURFACE output, surface characteristics can be determined using techniques that apply the same analysis as AERSURFACE. In the case of prognostic meteorological data, the surface characteristics associated with the prognostic meteorological model output for the representative grid cell should be used.<sup>102 103</sup> Furthermore, since the spatial scope of each variable could be different, representativeness should be judged for each variable separately. For example, for a variable such as wind direction, the data should ideally be collected near plume height to be adequately representative, especially for sources located in complex terrain. Whereas, for a variable such as temperature, data from a station several kilometers away from the source may be considered to be adequately representative. More information about meteorological data, representativeness, and surface characteristics can be found in the AERMOD Implementation Guide.<sup>76</sup>

c. Regulatory application of CTDMPPLUS requires the input of multi-level measurements of wind speed, direction, temperature, and turbulence from an appropriately sited meteorological tower. The measurements should be obtained up to the representative plume height(s) of interest. Plume heights of interest can be determined by use of screening procedures such as CTSCREEN.

d. Regulatory application of OCD requires meteorological data over land and over water.

The over land or surface data, processed through PCRAMMET<sup>96</sup> or MPRM,<sup>97</sup> that provides hourly stability class, wind direction and speed, ambient temperature, and mixing height, are required. Data over water requires hourly mixing height, relative humidity, air temperature, and water surface temperature. Missing winds are substituted with the surface winds. Vertical wind direction shear, vertical temperature gradient, and turbulence intensities are optional.

e. The model user should acquire enough meteorological data to ensure that worst-case meteorological conditions are adequately represented in the model results. The use of 5 years of adequately representative NWS or comparable meteorological data, at least 1 year of site-specific, or at least 3 years of prognostic meteorological data, are required. If 1 year or more, up to 5 years, of site-specific data are available, these data are preferred for use in air quality analyses. Depending on completeness of the data record, consecutive years of NWS, site-specific, or prognostic data are preferred. Such data must be subjected to quality assurance procedures as described in section 8.4.4.2.

f. Objective analysis in meteorological modeling is to improve meteorological analyses (the “*first guess field*”) used as initial conditions for prognostic meteorological models by incorporating information from meteorological observations. Direct and indirect (using remote sensing techniques) observations of temperature, humidity, and wind from surface and radiosonde reports are commonly employed to improve these analysis fields. For long-range transport applications, it is recommended that objective analysis procedures, using direct and indirect meteorological observations, be employed in preparing input fields to produce prognostic meteorological datasets. The length of record of observations should conform to recommendations outlined in paragraph 8.4.2(e) for prognostic meteorological model datasets.

#### 8.4.3 National Weather Service Data

##### 8.4.3.1 Discussion

a. The NWS meteorological data are routinely available and familiar to most model users. Although the NWS does not provide direct measurements of all the needed dispersion model input variables, methods have been developed and successfully used to translate the basic NWS data to the needed model input. Site-specific measurements of model input parameters have been made for many modeling studies, and those methods and techniques are becoming more widely applied, especially in situations such as complex terrain applications, where available NWS data are not adequately representative. However, there are many modeling applications where NWS data are adequately representative and the applications still rely heavily on the NWS data.

b. Many models use the standard hourly weather observations available from the National Centers for Environmental

Information (NCEI).<sup>b</sup> These observations are then preprocessed before they can be used in the models. Prior to the advent of ASOS in the early 1990's, the standard “hourly” weather observation was a human-based observation reflecting a single 2-minute average generally taken about 10 minutes before the hour. However, beginning in January 2000 for first-order stations and in March 2005 for all stations, the NCEI has archived the 1-minute ASOS wind data (*i.e.*, the rolling 2-minute average winds) for the NWS ASOS sites. The AERMINUTE processor<sup>95</sup> was developed to reduce the number of calm and missing hours in AERMET processing by substituting standard hourly observations with full hourly average winds calculated from 1-minute ASOS wind data.

##### 8.4.3.2 Recommendations

a. The preferred models listed in appendix A all accept, as input, the NWS meteorological data preprocessed into model compatible form. If NWS data are judged to be adequately representative for a specific modeling application, they may be used. The NCEI makes available surface<sup>104 105</sup> and upper air<sup>106</sup> meteorological data online and in CD-ROM format. Upper air data are also available at the Earth System Research Laboratory Global Systems Divisions Web site (<http://esrl.noaa.gov/gsd>).

b. Although most NWS wind measurements are made at a standard height of 10 m, the actual anemometer height should be used as input to the preferred meteorological processor and model.

c. Standard hourly NWS wind directions are reported to the nearest 10 degrees. Due to the coarse resolution of these data, a specific set of randomly generated numbers has been developed by the EPA and should be used when processing standard hourly NWS data for use in the preferred EPA models to ensure a lack of bias in wind direction assignments within the models.

d. Beginning with year 2000, NCEI began archiving 2-minute winds, reported every minute to the nearest degree for NWS ASOS sites. The AERMINUTE processor was developed to read those winds and calculate hourly average winds for input to AERMET. When such data are available for the NWS ASOS site being processed, the AERMINUTE processor should be used, in most cases, to calculate hourly average wind speed and direction when processing NWS ASOS data for input to AERMOD.<sup>93</sup>

e. Data from universities, FAA, military stations, industry and pollution control agencies may be used if such data are equivalent in accuracy and detail (*e.g.*, siting criteria, frequency of observations, data completeness, etc.) to the NWS data, they are judged to be adequately representative for the particular application, and have undergone quality assurance checks.

f. After valid data retrieval requirements have been met,<sup>107</sup> large number of hours in the record having missing data should be treated according to an established data substitution protocol provided that adequately representative alternative data are

available. Data substitution guidance is provided in section 5.3 of reference.<sup>107</sup> If no representative alternative data are available for substitution, the absent data should be coded as missing using missing data codes appropriate to the applicable meteorological pre-processor. Appropriate model options for treating missing data, if available in the model, should be employed.

#### 8.4.4 Site-Specific Data

##### 8.4.4.1 Discussion

a. Spatial or geographical representativeness is best achieved by collection of all of the needed model input data in close proximity to the actual site of the source(s). Site-specific measured data are, therefore, preferred as model input, provided that appropriate instrumentation and quality assurance procedures are followed, and that the data collected are adequately representative (free from inappropriate local or microscale influences) and compatible with the input requirements of the model to be used. It should be noted that, while site-specific measurements are frequently made “on-property” (*i.e.*, on the source's premises), acquisition of adequately representative site-specific data does not preclude collection of data from a location off property. Conversely, collection of meteorological data on a source's property does not of itself guarantee adequate representativeness. For help in determining representativeness of site-specific measurements, technical guidance<sup>107</sup> is available. Site-specific data should always be reviewed for representativeness and adequacy by an experienced meteorologist, atmospheric scientist, or other qualified scientist in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

##### 8.4.4.2 Recommendations

a. The EPA guidance<sup>107</sup> provides recommendations on the collection and use of site-specific meteorological data. Recommendations on characteristics, siting, and exposure of meteorological instruments and on data recording, processing, completeness requirements, reporting, and archiving are also included. This publication should be used as a supplement to other limited guidance on these subjects.<sup>5 91 108 109</sup> Detailed information on quality assurance is also available.<sup>110</sup> As a minimum, site-specific measurements of ambient air temperature, transport wind speed and direction, and the variables necessary to estimate atmospheric dispersion should be available in meteorological datasets to be used in modeling. Care should be taken to ensure that meteorological instruments are located to provide an adequately representative characterization of pollutant transport between sources and receptors of interest. The appropriate reviewing authority (paragraph 3.0(b)) is available to help determine the appropriateness of the measurement locations.

i. *Solar radiation measurements.* Total solar radiation or net radiation should be measured with a reliable pyranometer or net radiometer sited and operated in accordance with established site-specific meteorological guidance.<sup>107 110</sup>

<sup>b</sup> Formerly the National Climatic Data Center (NCDC).

ii. *Temperature measurements.*

Temperature measurements should be made at standard shelter height (2m) in accordance with established site-specific meteorological guidance.<sup>107</sup>

iii. *Temperature difference measurements.*

Temperature difference (DT) measurements should be obtained using matched thermometers or a reliable thermocouple system to achieve adequate accuracy. Siting, probe placement, and operation of DT systems should be based on guidance found in Chapter 3 of reference 107 and such guidance should be followed when obtaining vertical temperature gradient data. AERMET may employ the Bulk Richardson scheme, which requires measurements of temperature difference, in lieu of cloud cover or insolation data. To ensure correct application and acceptance, AERMOD users should consult with the appropriate reviewing authority (paragraph 3.0(b)) before using the Bulk Richardson scheme for their analysis.

iv. *Wind measurements.* For simulation of plume rise and dispersion of a plume emitted from a stack, characterization of the wind profile up through the layer in which the plume disperses is desirable. This is especially important in complex terrain and/or complex wind situations where wind measurements at heights up to hundreds of meters above stack base may be required in some circumstances. For tall stacks when site-specific data are needed, these winds have been obtained traditionally using meteorological sensors mounted on tall towers. A feasible alternative to tall towers is the use of meteorological remote sensing instruments (e.g., acoustic sounders or radar wind profilers) to provide winds aloft, coupled with 10-meter towers to provide the near-surface winds. Note that when site-specific wind measurements are used, AERMOD, at a minimum, requires wind observations at a height above ground between seven times the local surface roughness height and 100 m. (For additional requirements for AERMOD and CTDMPPLUS, see appendix A.) Specifications for wind measuring instruments and systems are contained in reference 107.

b. All processed site-specific data should be in the form of hourly averages for input to the dispersion model.

i. *Turbulence data.* There are several dispersion models that are capable of using direct measurements of turbulence (wind fluctuations) in the characterization of the vertical and lateral dispersion (e.g., CTDMPPLUS or AERMOD). When turbulence data are used to directly characterize the vertical and lateral dispersion, the averaging time for the turbulence measurements should be 1 hour. For technical guidance on processing of turbulence parameters for use in dispersion modeling, refer to the user's guide to the meteorological processor for each model (see section 8.4.2(a)).

ii. *Stability categories.* For dispersion models that employ P-G stability categories for the characterization of the vertical and lateral dispersion, the P-G stability categories, as originally defined, couple near-surface measurements of wind speed with subjectively determined insolation assessments based on hourly cloud cover and

ceiling height observations. The wind speed measurements are made at or near 10 m. The insolation rate is typically assessed using observations of cloud cover and ceiling height based on criteria outlined by Turner.<sup>72</sup> It is recommended that the P-G stability category be estimated using the Turner method with site-specific wind speed measured at or near 10 m and representative cloud cover and ceiling height.

Implementation of the Turner method, as well as considerations in determining representativeness of cloud cover and ceiling height in cases for which site-specific cloud observations are unavailable, may be found in section 6 of reference 107. In the absence of requisite data to implement the Turner method, the solar radiation/delta-T (SRDT) method or wind fluctuation statistics (i.e., the  $\sigma_E$  and  $\sigma_A$  methods) may be used.

iii. The SRDT method, described in section 6.4.4.2 of reference 107, is modified slightly from that published from earlier work<sup>111</sup> and has been evaluated with three site-specific databases.<sup>112</sup> The two methods of stability classification that use wind fluctuation statistics, the  $\sigma_E$  and  $\sigma_A$  methods, are also described in detail in section 6.4.4 of reference 107 (note applicable tables in section 6). For additional information on the wind fluctuation methods, several references are available.<sup>113 114 115 116</sup>

c. *Missing data substitution.* After valid data retrieval requirements have been met,<sup>107</sup> hours in the record having missing data should be treated according to an established data substitution protocol provided that adequately representative alternative data are available. Such protocols are usually part of the approved monitoring program plan. Data substitution guidance is provided in section 5.3 of reference 107. If no representative alternative data are available for substitution, the absent data should be coded as missing, using missing data codes appropriate to the applicable meteorological pre-processor. Appropriate model options for treating missing data, if available in the model, should be employed.

#### 8.4.5 Prognostic Meteorological Data

##### 8.4.5.1 Discussion

a. For some modeling applications, there may not be a representative NWS or comparable meteorological station available (e.g., complex terrain), and it may be cost prohibitive or infeasible to collect adequately representative site-specific data. For these cases, it may be appropriate to use prognostic meteorological data, if deemed adequately representative, in a regulatory modeling application. However, if prognostic meteorological data are not representative of transport and dispersion conditions in the area of concern, the collection of site-specific data is necessary.

b. The EPA has developed a processor, the MMIF,<sup>102</sup> to process MM5 (Mesoscale Model 5) or WRF (Weather Research and Forecasting) model data for input to various models including AERMOD. MMIF can process data for input to AERMET or AERMOD for a single grid cell or multiple grid cells. MMIF output has been found to compare favorably against observed data (site-specific or NWS).<sup>117</sup> Specific guidance

on processing MMIF for AERMOD can be found in reference 103. When using MMIF to process prognostic data for regulatory applications, the data should be processed to generate AERMET inputs and the data subsequently processed through AERMET for input to AERMOD. If an alternative method of processing data for input to AERMET is used, it must be approved by the appropriate reviewing authority (paragraph 3.0(b)).

#### 8.4.5.2 Recommendations

##### a. *Prognostic model evaluation.*

Appropriate effort by the applicant should be devoted to the process of evaluating the prognostic meteorological data. The modeling data should be compared to NWS observational data or other comparable data in an effort to show that the data are adequately replicating the observed meteorological conditions of the time periods modeled. An operational evaluation of the modeling data for all model years (i.e., statistical, graphical) should be completed.<sup>60</sup> The use of output from prognostic mesoscale meteorological models is contingent upon the concurrence with the appropriate reviewing authority (paragraph 3.0(b)) that the data are of acceptable quality, which can be demonstrated through statistical comparisons with meteorological observations aloft and at the surface at several appropriate locations.<sup>60</sup>

b. *Representativeness.* When processing MMIF data for use with AERMOD, the grid cell used for the dispersion modeling should be adequately spatially representative of the analysis domain. In most cases, this may be the grid cell containing the emission source of interest. Since the dispersion modeling may involve multiple sources and the domain may cover several grid cells, depending on grid resolution of the prognostic model, professional judgment may be needed to select the appropriate grid cell to use. In such cases, the selected grid cells should be adequately representative of the entire domain.

c. *Grid resolution.* The grid resolution of the prognostic meteorological data should be considered and evaluated appropriately, particularly for projects involving complex terrain. The operational evaluation of the modeling data should consider whether a finer grid resolution is needed to ensure that the data are representative. The use of output from prognostic mesoscale meteorological models is contingent upon the concurrence with the appropriate reviewing authority (paragraph 3.0(b)) that the data are of acceptable quality.

#### 8.4.6 Treatment of Near-Calms and Calms

##### 8.4.6.1 Discussion

a. Treatment of calm or light and variable wind poses a special problem in modeling applications since steady-state Gaussian plume models assume that concentration is inversely proportional to wind speed, depending on model formulations. Procedures have been developed to prevent the occurrence of overly conservative concentration estimates during periods of calms. These procedures acknowledge that a steady-state Gaussian plume model does not apply during calm conditions, and that our knowledge of wind patterns and plume

behavior during these conditions does not, at present, permit the development of a better technique. Therefore, the procedures disregard hours that are identified as calm. The hour is treated as missing and a convention for handling missing hours is recommended. With the advent of the AERMINUTE processor, when processing NWS ASOS data, the inclusion of hourly averaged winds from AERMINUTE will, in some instances, dramatically reduce the number of calm and missing hours, especially when the ASOS wind are derived from a sonic anemometer. To alleviate concerns about these issues, especially those introduced with AERMINUTE, the EPA implemented a wind speed threshold in AERMET for use with ASOS derived winds.<sup>93,94</sup> Winds below the threshold will be treated as calms.

b. AERMOD, while fundamentally a steady-state Gaussian plume model, contains algorithms for dealing with low wind speed (near calm) conditions. As a result, AERMOD can produce model estimates for conditions where the wind speed may be less than 1 m/s, but still greater than the instrument threshold. Required input to AERMET for site-specific data, the meteorological processor for AERMOD, includes a threshold wind speed and a reference wind speed. The threshold wind speed is the greater of the threshold of the instrument used to collect the wind speed data or wind direction sensor.<sup>107</sup> The reference wind speed is selected by the model as the lowest level of non-missing wind speed and direction data where the speed is greater than the wind speed threshold, and the height of the measurement is between seven times the local surface roughness length and 100 m. If the only valid observation of the reference wind speed between these heights is less than the threshold, the hour is considered calm, and no concentration is calculated. None of the observed wind speeds in a measured wind profile that are less than the threshold speed are used in construction of the modeled wind speed profile in AERMOD.

8.4.6.2 Recommendations

a. Hourly concentrations calculated with steady-state Gaussian plume models using calms should not be considered valid; the wind and concentration estimates for these hours should be disregarded and considered to be missing. Model predicted concentrations for 3-, 8-, and 24-hour averages should be calculated by dividing the sum of the hourly concentrations for the period by the number of valid or non-missing hours. If the total number of valid hours is less than 18 for 24-hour averages, less than 6 for 8-hour averages, or less than 3 for 3-hour averages, the total concentration should be divided by 18 for the 24-hour average, 6 for the 8-hour average, and 3 for the 3-hour average. For annual averages, the sum of all valid hourly concentrations is divided by the number of non-calm hours during the year. AERMOD has been coded to implement these instructions. For hours that are calm or missing, the AERMOD hourly concentrations will be zero. For other models listed in appendix A, a post-processor computer program, CALMPRO<sup>118</sup> has been prepared, is

available on the EPA's SCRAM Web site (section 2.3), and should be used.

b. Stagnant conditions that include extended periods of calms often produce high concentrations over wide areas for relatively long averaging periods. The standard steady-state Gaussian plume models are often not applicable to such situations. When stagnation conditions are of concern, other modeling techniques should be considered on a case-by-case basis (*see* also section 7.2.1.2).

c. When used in steady-state Gaussian plume models other than AERMOD, measured site-specific wind speeds of less than 1 m/s but higher than the response threshold of the instrument should be input as 1 m/s; the corresponding wind direction should also be input. Wind observations below the response threshold of the instrument should be set to zero, with the input file in ASCII format. For input to AERMOD, no such adjustment should be made to the site-specific wind data, as AERMOD has algorithms to account for light or variable winds as discussed in section 8.4.6.1(a). For NWS ASOS data, especially data using the 1-minute ASOS winds, a wind speed threshold option is allowed with a recommended speed of 0.5 m/s.<sup>93</sup> When using prognostic data processed by MMIF, a 0.5 m/s threshold is also invoked by MMIF for input to AERMET. Observations with wind speeds less than the threshold are considered calm, and no concentration is calculated. In all cases involving steady-state Gaussian plume models, calm hours should be treated as missing, and concentrations should be calculated as in paragraph (a) of this subsection.

## 9.0 Regulatory Application of Models

### 9.1 Discussion

a. Standardized procedures are valuable in the review of air quality modeling and data analyses conducted to support SIP submittals and revisions, NSR, or other EPA requirements to ensure consistency in their regulatory application. This section recommends procedures specific to NSR that facilitate some degree of standardization while at the same time allowing the flexibility needed to assure the technically best analysis for each regulatory application. For SIP attainment demonstrations, refer to the appropriate EPA guidance<sup>51,60</sup> for the recommended procedures.

b. Air quality model estimates, especially with the support of measured air quality data, are the preferred basis for air quality demonstrations. A number of actions have been taken to ensure that the best air quality model is used correctly for each regulatory application and that it is not arbitrarily imposed.

- First, the *Guideline* clearly recommends that the most appropriate model be used in each case. Preferred models are identified, based on a number of factors, for many uses.

- Second, the preferred models have been subjected to a systematic performance evaluation and a scientific peer review. Statistical performance measures, including measures of difference (or residuals) such as bias, variance of difference and gross variability of the difference, and measures of

correlation such as time, space, and time and space combined, as described in section 2.1.1, were generally followed.

- Third, more specific information has been provided for considering the incorporation of new models into the *Guideline* (section 3.1), and the *Guideline* contains procedures for justifying the case-by-case use of alternative models and obtaining EPA approval (section 3.2).

c. Air quality modeling is the preferred basis for air quality demonstrations. Nevertheless, there are rare circumstances where the performance of the preferred air quality model may be shown to be less than reasonably acceptable or where no preferred air quality model, screening model or technique, or alternative model are suitable for the situation. In these unique instances, there is the possibility of assuring compliance and establishing emissions limits for an existing source solely on the basis of observed air quality data in lieu of an air quality modeling analysis. Comprehensive air quality monitoring in the vicinity of the existing source with proposed modifications will be necessary in these cases. The same attention should be given to the detailed analyses of the air quality data as would be applied to a model performance evaluation.

d. The current levels and forms of the NAAQS for the six criteria pollutants can be found on the EPA's NAAQS Web site at <https://www.epa.gov/criteria-air-pollutants>. As required by the CAA, the NAAQS are subjected to extensive review every 5 years and the standards, including the level and the form, may be revised as part of that review. The criteria pollutants have either long-term (annual or quarterly) and/or short-term (24-hour or less) forms that are not to be exceeded more than a certain frequency over a period of time (*e.g.*, no exceedance on a rolling 3-month average, no more than once per year, or no more than once per year averaged over 3 years), are averaged over a period of time (*e.g.*, an annual mean or an annual mean averaged over 3 years), or are some percentile that is averaged over a period of time (*e.g.*, annual 99th or 98th percentile averaged over 3 years). The 3-year period for ambient monitoring design values does not dictate the length of the data periods recommended for modeling (*i.e.*, 5 years of NWS meteorological data, at least 1 year of site-specific, or at least 3 years of prognostic meteorological data).

e. This section discusses general recommendations on the regulatory application of models for the purposes of NSR, including PSD permitting, and particularly for estimating design concentration(s), appropriately comparing these estimates to NAAQS and PSD increments, and developing emissions limits. This section also provides the criteria necessary for considering use of an analysis based on measured ambient data in lieu of modeling as the sole basis for demonstrating compliance with NAAQS and PSD increments.

### 9.2 Recommendations

#### 9.2.1 Modeling Protocol

a. Every effort should be made by the appropriate reviewing authority (paragraph



3.0(b)) to meet with all parties involved in either a SIP submission or revision or a PSD permit application prior to the start of any work on such a project. During this meeting, a protocol should be established between the preparing and reviewing parties to define the procedures to be followed, the data to be collected, the model to be used, and the analysis of the source and concentration data to be performed. An example of the content for such an effort is contained in the Air Quality Analysis Checklist posted on the EPA's SCRAM Web site (section 2.3). This checklist suggests the appropriate level of detail to assess the air quality resulting from the proposed action. Special cases may require additional data collection or analysis and this should be determined and agreed upon at the pre-application meeting. The protocol should be written and agreed upon by the parties concerned, although it is not intended that this protocol be a binding, formal legal document. Changes in such a protocol or deviations from the protocol are often necessary as the data collection and analysis progresses. However, the protocol establishes a common understanding of how the demonstration required to meet regulatory requirements will be made.

#### 9.2.2 Design Concentration and Receptor Sites

a. Under the PSD permitting program, an air quality analysis for criteria pollutants is required to demonstrate that emissions from the construction or operation of a proposed new source or modification will not cause or contribute to a violation of the NAAQS or PSD increments.

i. For a NAAQS assessment, the design concentration is the combination of the appropriate background concentration (section 8.3) with the estimated modeled impact of the proposed source. The NAAQS design concentration is then compared to the applicable NAAQS.

ii. For a PSD increment assessment, the design concentration includes impacts occurring after the appropriate baseline date from all increment-consuming and increment-expanding sources. The PSD increment design concentration is then compared to the applicable PSD increment.

b. The specific form of the NAAQS for the pollutant(s) of concern will also influence how the background and modeled data should be combined for appropriate comparison with the respective NAAQS in such a modeling demonstration. Given the potential for revision of the form of the NAAQS and the complexities of combining background and modeled data, specific details on this process can be found in the applicable modeling guidance available on the EPA's SCRAM Web site (section 2.3). Modeled concentrations should not be rounded before comparing the resulting design concentration to the NAAQS or PSD increments. Ambient monitoring and dispersion modeling address different issues and needs relative to each aspect of the overall air quality assessment.

c. The PSD increments for criteria pollutants are listed in 40 CFR 52.21(c) and 40 CFR 51.166(c). For short-term increments, these maximum allowable increases in pollutant concentrations may be exceeded

once per year at each site, while the annual increment may not be exceeded. The highest, second-highest increase in estimated concentrations for the short-term averages, as determined by a model, must be less than or equal to the permitted increment. The modeled annual averages must not exceed the increment.

d. Receptor sites for refined dispersion modeling should be located within the modeling domain (section 8.1). In designing a receptor network, the emphasis should be placed on receptor density and location, not total number of receptors. Typically, the density of receptor sites should be progressively more resolved near the new or modifying source, areas of interest, and areas with the highest concentrations with sufficient detail to determine where possible violations of a NAAQS or PSD increments are most likely to occur. The placement of receptor sites should be determined on a case-by-case basis, taking into consideration the source characteristics, topography, climatology, and monitor sites. Locations of particular importance include: (1) The area of maximum impact of the point source; (2) the area of maximum impact of nearby sources; and (3) the area where all sources combine to cause maximum impact. Depending on the complexities of the source and the environment to which the source is located, a dense array of receptors may be required in some cases. In order to avoid unreasonably large computer runs due to an excessively large array of receptors, it is often desirable to model the area twice. The first model run would use a moderate number of receptors more resolved near the new or modifying source and over areas of interest. The second model run would modify the receptor network from the first model run with a denser array of receptors in areas showing potential for high concentrations and possible violations, as indicated by the results of the first model run. Accordingly, the EPA neither anticipates nor encourages that numerous iterations of modeling runs be made to continually refine the receptor network.

#### 9.2.3 NAAQS and PSD Increments Compliance Demonstrations for New or Modifying Sources

a. As described in this subsection, the recommended procedure for conducting either a NAAQS or PSD increments assessment under PSD permitting is a multi-stage approach that includes the following two stages:

i. The EPA describes the first stage as a single-source impact analysis, since this stage involves considering only the impact of the new or modifying source. There are two possible levels of detail in conducting a single-source impact analysis with the model user beginning with use of a screening model and proceeding to use of a refined model as necessary.

ii. The EPA describes the second stage as a cumulative impact analysis, since it takes into account all sources affecting the air quality in an area. In addition to the project source impact, this stage includes consideration of background, which includes contributions from nearby sources and other

sources (e.g., natural, minor, and distant major sources).

b. Each stage should involve increasing complexity and details, as required, to fully demonstrate that a new or modifying source will not cause or contribute to a violation of any NAAQS or PSD increment. As such, starting with a single-source impact analysis is recommended because, where the analysis at this stage is sufficient to demonstrate that a source will not cause or contribute to any potential violation, this may alleviate the need for a more time-consuming and comprehensive cumulative modeling analysis.

c. The single-source impact analysis, or first stage of an air quality analysis, should begin by determining the potential of a proposed new or modifying source to cause or contribute to a NAAQS or PSD increment violation. In certain circumstances, a screening model or technique may be used instead of the preferred model because it will provide estimated worst-case ambient impacts from the proposed new or modifying source. If these worst case ambient concentration estimates indicate that the source will not cause or contribute to any potential violation of a NAAQS or PSD increment, then the screening analysis should generally be sufficient for the required demonstration under PSD. If the ambient concentration estimates indicate that the source's emissions have the potential to cause or contribute to a violation, then the use of a refined model to estimate the source's impact should be pursued. The refined modeling analysis should use a model or technique consistent with the *Guideline* (either a preferred model or technique) or an alternative model or technique) and follow the requirements and recommendations for model inputs outlined in section 8. If the ambient concentration increase predicted with refined modeling indicates that the source will not cause or contribute to any potential violation of a NAAQS or PSD increment, then the refined analysis should generally be sufficient for the required demonstration under PSD. However, if the ambient concentration estimates from the refined modeling analysis indicate that the source's emissions have the potential to cause or contribute to a violation, then a cumulative impact analysis should be undertaken. The receptors that indicate the location of significant ambient impacts should be used to define the modeling domain for use in the cumulative impact analysis (section 8.2.2).

d. The cumulative impact analysis, or the second stage of an air quality analysis, should be conducted with the same refined model or technique to characterize the project source and then include the appropriate background concentrations (section 8.3). The resulting design concentrations should be used to determine whether the source will cause or contribute to a NAAQS or PSD increment violation. This determination should be based on: (1) The appropriate design concentration for each applicable NAAQS (and averaging period); and (2) whether the source's emissions cause or contribute to a violation at the time and location of any modeled

violation (*i.e.*, when and where the predicted design concentration is greater than the NAAQS). For PSD increments, the cumulative impact analysis should also consider the amount of the air quality increment that has already been consumed by other sources, or, conversely, whether increment has expanded relative to the baseline concentration. Therefore, the applicant should model the existing or permitted nearby increment-consuming and increment-expanding sources, rather than using past modeling analyses of those sources as part of background concentration. This would permit the use of newly acquired data or improved modeling techniques if such data and/or techniques have become available since the last source was permitted.

#### 9.2.3.1 Considerations in Developing Emissions Limits

a. Emissions limits and resulting control requirements should be established to provide for compliance with each applicable NAAQS (and averaging period) and PSD increment. It is possible that multiple emissions limits will be required for a source to demonstrate compliance with several criteria pollutants (and averaging periods) and PSD increments. Case-by-case determinations must be made as to the appropriate form of the limits, *i.e.*, whether the emissions limits restrict the emission factor (*e.g.*, limiting lb/MMBTU), the emission rate (*e.g.*, lb/hr), or both. The appropriate reviewing authority (paragraph 3.0(b)) and appropriate EPA guidance should be consulted to determine the appropriate emissions limits on a case-by-case basis.

#### 9.2.4 Use of Measured Data in Lieu of Model Estimates

a. As described throughout the *Guideline*, modeling is the preferred method for demonstrating compliance with the NAAQS and PSD increments and for determining the most appropriate emissions limits for new and existing sources. When a preferred model or adequately justified and approved alternative model is available, model results, including the appropriate background, are sufficient for air quality demonstrations and establishing emissions limits, if necessary. In instances when the modeling technique available is only a screening technique, the addition of air quality monitoring data to the analysis may lend credence to the model results. However, air quality monitoring data alone will normally not be acceptable as the sole basis for demonstrating compliance with the NAAQS and PSD increments or for determining emissions limits.

b. There may be rare circumstances where the performance of the preferred air quality model will be shown to be less than reasonably acceptable when compared with air quality monitoring data measured in the vicinity of an existing source. Additionally, there may not be an applicable preferred air quality model, screening technique, or justifiable alternative model suitable for the situation. In these unique instances, there may be the possibility of establishing emissions limits and demonstrating compliance with the NAAQS and PSD increments solely on the basis of analysis of observed air quality data in lieu of an air

quality modeling analysis. However, only in the case of a modification to an existing source should air quality monitoring data alone be a basis for determining adequate emissions limits or for demonstration that the modification will not cause or contribute to a violation of any NAAQS or PSD increment.

c. The following items should be considered prior to the acceptance of an analysis of measured air quality data as the sole basis for an air quality demonstration or determining an emissions limit:

- i. Does a monitoring network exist for the pollutants and averaging times of concern in the vicinity of the existing source?
- ii. Has the monitoring network been designed to locate points of maximum concentration?
- iii. Do the monitoring network and the data reduction and storage procedures meet EPA monitoring and quality assurance requirements?
- iv. Do the dataset and the analysis allow impact of the most important individual sources to be identified if more than one source or emission point is involved?
- v. Is at least one full year of valid ambient data available?
- vi. Can it be demonstrated through the comparison of monitored data with model results that available air quality models and techniques are not applicable?

d. Comprehensive air quality monitoring in the area affected by the existing source with proposed modifications will be necessary in these cases. Additional meteorological monitoring may also be necessary. The appropriate number of air quality and meteorological monitors from a scientific and technical standpoint is a function of the situation being considered. The source configuration, terrain configuration, and meteorological variations all have an impact on number and optimal placement of monitors. Decisions on the monitoring network appropriate for this type of analysis can only be made on a case-by-case basis.

e. Sources should obtain approval from the appropriate reviewing authority (paragraph 3.0(b)) and the EPA Regional Office for the monitoring network prior to the start of monitoring. A monitoring protocol agreed to by all parties involved is necessary to assure that ambient data are collected in a consistent and appropriate manner. The design of the network, the number, type, and location of the monitors, the sampling period, averaging time, as well as the need for meteorological monitoring or the use of mobile sampling or plume tracking techniques, should all be specified in the protocol and agreed upon prior to start-up of the network.

f. Given the uniqueness and complexities of these rare circumstances, the procedures can only be established on a case-by-case basis for analyzing the source's emissions data and the measured air quality monitoring data, and for projecting with a reasoned basis the air quality impact of a proposed modification to an existing source in order to demonstrate that emissions from the construction or operation of the modification will not cause or contribute to a violation of the applicable NAAQS and PSD increment, and to determine adequate emissions limits.

The same attention should be given to the detailed analyses of the air quality data as would be applied to a comprehensive model performance evaluation. In some cases, the monitoring data collected for use in the performance evaluation of preferred air quality models, screening technique, or existing alternative models may help inform the development of a suitable new alternative model. Early coordination with the appropriate reviewing authority (paragraph 3.0(b)) and the EPA Regional Office is fundamental with respect to any potential use of measured data in lieu of model estimates.

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## Appendix A to Appendix W of Part 51—Summaries of Preferred Air Quality Models

### Table of Contents

- A.0 Introduction and Availability
- A.1 AERMOD (AMS/EPA Regulatory Model)
- A.2 CTDMPLUS (Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations)
- A.3 OCD (Offshore and Coastal Dispersion Model)

#### A.0 Introduction and Availability

(1) This appendix summarizes key features of refined air quality models preferred for specific regulatory applications. For each model, information is provided on availability, approximate cost (where applicable), regulatory use, data input, output format and options, simulation of atmospheric physics, and accuracy. These models may be used without a formal demonstration of applicability provided they satisfy the recommendations for regulatory use; not all options in the models are necessarily recommended for regulatory use.

(2) Many of these models have been subjected to a performance evaluation using comparisons with observed air quality data. Where possible, several of the models contained herein have been subjected to evaluation exercises, including: (1) Statistical performance tests recommended by the American Meteorological Society, and (2) peer scientific reviews. The models in this appendix have been selected on the basis of the results of the model evaluations, experience with previous use, familiarity of the model to various air quality programs, and the costs and resource requirements for use.

(3) Codes and documentation for all models listed in this appendix are available from the EPA's Support Center for Regulatory Air Models (SCRAM) Web site at <https://www.epa.gov/scramp>. Codes and documentation may also be available from the National Technical Information Service (NTIS), <http://www.ntis.gov>, and, when available, are referenced with the appropriate NTIS accession number.

#### A.1 AERMOD (AMS/EPA Regulatory Model)

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##### Availability

The model codes and associated documentation are available on EPA's SCRAM Web site (paragraph A.0(3)).

##### Abstract

AERMOD is a steady-state plume dispersion model for assessment of pollutant concentrations from a variety of sources. AERMOD simulates transport and dispersion from multiple point, area, or volume sources based on an up-to-date characterization of the atmospheric boundary layer. Sources may be located in rural or urban areas, and receptors may be located in simple or complex terrain. AERMOD accounts for building wake effects (*i.e.*, plume downwash) based on the PRIME building downwash algorithms. The model employs hourly sequential preprocessed meteorological data to estimate concentrations for averaging times from 1-hour to 1-year (also multiple years). AERMOD can be used to estimate the concentrations of nonreactive pollutants from highway traffic. AERMOD also handles unique modeling problems associated with aluminum reduction plants, and other industrial sources where plume rise and downwash effects from stationary buoyant line sources are important. AERMOD is designed to operate in concert with two preprocessor codes: AERMET processes meteorological data for input to AERMOD, and AERMAP processes terrain elevation data and generates receptor and hill height information for input to AERMOD.

##### a. Regulatory Use

(1) AERMOD is appropriate for the following applications:

- Point, volume, and area sources;

- Buoyant, elevated line sources (*e.g.*, aluminum reduction plants);
- Mobile sources;
- Surface, near-surface, and elevated releases;
- Rural or urban areas;
- Simple and complex terrain;
- Transport distances over which steady-state assumptions are appropriate, up to 50km;
- 1-hour to annual averaging times; and
- Continuous toxic air emissions.

(2) For regulatory applications of AERMOD, the regulatory default option should be set, *i.e.*, the parameter DFAULT should be employed in the MODELOPT record in the COntrol Pathway. The DFAULT option requires the use of meteorological data processed with the regulatory options in AERMET, the use of terrain elevation data processed through the AERMAP terrain processor, stack-tip downwash, sequential date checking, and does not permit the use of the model in the SCREEN mode. In the regulatory default mode, pollutant half-life or decay options are not employed, except in the case of an urban source of sulfur dioxide where a 4-hour half-life is applied. Terrain elevation data from the U.S. Geological Survey (USGS) 7.5-Minute Digital Elevation Model (DEM), or equivalent (approx. 30-meter resolution), (processed through AERMAP) should be used in all applications. Starting in 2011, data from the National Elevation Dataset (NED, <https://nationalmap.gov/elevation.html>) can also be used in AERMOD, which includes a range of resolutions, from 1-m to 2 arc seconds and such high resolution would always be preferred. In some cases, exceptions from the terrain data requirement may be made in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

##### b. Input Requirements

(1) Source data: Required inputs include source type, location, emission rate, stack height, stack inside diameter, stack gas exit velocity, stack gas exit temperature, area and volume source dimensions, and source base elevation. For point sources subject to the influence of building downwash, direction-specific building dimensions (processed through the BPIPPRM building processor) should be input. Variable emission rates are optional. Buoyant line sources require coordinates of the end points of the line, release height, emission rate, average line source width, average building width, average spacing between buildings, and average line source buoyancy parameter. For mobile sources, traffic volume; emission factor, source height, and mixing zone width are needed to determine appropriate model inputs.

(2) Meteorological data: The AERMET meteorological preprocessor requires input of surface characteristics, including surface roughness ( $z_0$ ), Bowen ratio, and albedo, as well as, hourly observations of wind speed between 7zo and 100 m (reference wind speed measurement from which a vertical profile can be developed), wind direction, cloud cover, and temperature between  $z_0$  and 100 m (reference temperature measurement from which a vertical profile can be developed). Meteorological data can be in the

form of observed data or prognostic modeled data as discussed in paragraph 8.4.1(d). Surface characteristics may be varied by wind sector and by season or month. When using observed meteorological data, a morning sounding (in National Weather Service format) from a representative upper air station is required. Latitude, longitude, and time zone of the surface, site-specific (if applicable) and upper air meteorological stations are required. The wind speed starting threshold is also required in AERMET for applications involving site-specific data. When using prognostic data, modeled profiles of temperature and winds are input to AERMET. These can be hourly or a time that represents a morning sounding. Additionally, measured profiles of wind, temperature, vertical and lateral turbulence may be required in certain applications (e.g., in complex terrain) to adequately represent the meteorology affecting plume transport and dispersion. Optionally, measurements of solar and/or net radiation may be input to AERMET. Two files are produced by the AERMET meteorological preprocessor for input to the AERMOD dispersion model. When using observed data, the surface file contains observed and calculated surface variables, one record per hour. For applications with multi-level site-specific meteorological data, the profile contains the observations made at each level of the meteorological tower (or remote sensor). When using prognostic data, the surface file contains surface variables calculated by the prognostic model and AERMET. The profile file contains the observations made at each level of a meteorological tower (or remote sensor), the one-level observations taken from other representative data (e.g., National Weather Service surface observations), one record per level per hour, or in the case of prognostic data, the prognostic modeled values of temperature and winds at user-specified levels.

(i) Data used as input to AERMET should possess an adequate degree of representativeness to ensure that the wind, temperature and turbulence profiles derived by AERMOD are both laterally and vertically representative of the source impact area. The adequacy of input data should be judged independently for each variable. The values for surface roughness, Bowen ratio, and albedo should reflect the surface characteristics in the vicinity of the meteorological tower or representative grid cell when using prognostic data, and should be adequately representative of the modeling domain. Finally, the primary atmospheric input variables, including wind speed and direction, ambient temperature, cloud cover, and a morning upper air sounding, should also be adequately representative of the source area when using observed data.

(ii) For applications involving the use of site-specific meteorological data that includes turbulences parameters (i.e., sigma-theta and/or sigma-w), the application of the ADJ\_U\* option in AERMET would require approval as an alternative model application under section 3.2.

(iii) For recommendations regarding the length of meteorological record needed to perform a regulatory analysis with AERMOD, see section 8.4.2.

(3) Receptor data: Receptor coordinates, elevations, height above ground, and hill height scales are produced by the AERMAP terrain preprocessor for input to AERMOD. Discrete receptors and/or multiple receptor grids, Cartesian and/or polar, may be employed in AERMOD. AERMAP requires input of DEM or NED terrain data produced by the USGS, or other equivalent data. AERMAP can be used optionally to estimate source elevations.

#### c. Output

Printed output options include input information, high concentration summary tables by receptor for user-specified averaging periods, maximum concentration summary tables, and concurrent values summarized by receptor for each day processed. Optional output files can be generated for: A listing of occurrences of exceedances of user-specified threshold value; a listing of concurrent (raw) results at each receptor for each hour modeled, suitable for post-processing; a listing of design values that can be imported into graphics software for plotting contours; a listing of results suitable for NAAQS analyses including NAAQS exceedances and culpability analyses; an unformatted listing of raw results above a threshold value with a special structure for use with the TOXX model component of TOXST; a listing of concentrations by rank (e.g., for use in quantile-quantile plots); and a listing of concentrations, including arc-maximum normalized concentrations, suitable for model evaluation studies.

#### d. Type of Model

AERMOD is a steady-state plume model, using Gaussian distributions in the vertical and horizontal for stable conditions, and in the horizontal for convective conditions. The vertical concentration distribution for convective conditions results from an assumed bi-Gaussian probability density function of the vertical velocity.

#### e. Pollutant Types

AERMOD is applicable to primary pollutants and continuous releases of toxic and hazardous waste pollutants. Chemical transformation is treated by simple exponential decay.

#### f. Source-Receptor Relationships

AERMOD applies user-specified locations for sources and receptors. Actual separation between each source-receptor pair is used. Source and receptor elevations are user input or are determined by AERMAP using USGS DEM or NED terrain data. Receptors may be located at user-specified heights above ground level.

#### g. Plume Behavior

(1) In the convective boundary layer (CBL), the transport and dispersion of a plume is characterized as the superposition of three modeled plumes: (1) The direct plume (from the stack); (2) the indirect plume; and (3) the penetrated plume, where the indirect plume accounts for the lofting of a buoyant plume near the top of the boundary layer, and the penetrated plume accounts for the portion of a plume that, due to its buoyancy, penetrates above the mixed layer, but can disperse

downward and re-enter the mixed layer. In the CBL, plume rise is superposed on the displacements by random convective velocities (Weil *et al.*, 1997).

(2) In the stable boundary layer, plume rise is estimated using an iterative approach to account for height-dependent lapse rates, similar to that in the CTDMPLUS model (see A.2 in this appendix).

(3) Stack-tip downwash and buoyancy induced dispersion effects are modeled. Building wake effects are simulated for stacks subject to building downwash using the methods contained in the PRIME downwash algorithms (Schulman, *et al.*, 2000). For plume rise affected by the presence of a building, the PRIME downwash algorithm uses a numerical solution of the mass, energy and momentum conservation laws (Zhang and Ghoniem, 1993). Streamline deflection and the position of the stack relative to the building affect plume trajectory and dispersion. Enhanced dispersion is based on the approach of Weil (1996). Plume mass captured by the cavity is well-mixed within the cavity. The captured plume mass is re-emitted to the far wake as a volume source.

(4) For elevated terrain, AERMOD incorporates the concept of the critical dividing streamline height, in which flow below this height remains horizontal, and flow above this height tends to rise up and over terrain (Snyder *et al.*, 1985). Plume concentration estimates are the weighted sum of these two limiting plume states. However, consistent with the steady-state assumption of uniform horizontal wind direction over the modeling domain, straight-line plume trajectories are assumed, with adjustment in the plume/receptor geometry used to account for the terrain effects.

#### h. Horizontal Winds

Vertical profiles of wind are calculated for each hour based on measurements and surface-layer similarity (scaling) relationships. At a given height above ground, for a given hour, winds are assumed constant over the modeling domain. The effect of the vertical variation in horizontal wind speed on dispersion is accounted for through simple averaging over the plume depth.

#### i. Vertical Wind Speed

In convective conditions, the effects of random vertical updraft and downdraft velocities are simulated with a bi-Gaussian probability density function. In both convective and stable conditions, the mean vertical wind speed is assumed equal to zero.

#### j. Horizontal Dispersion

Gaussian horizontal dispersion coefficients are estimated as continuous functions of the parameterized (or measured) ambient lateral turbulence and also account for buoyancy-induced and building wake-induced turbulence. Vertical profiles of lateral turbulence are developed from measurements and similarity (scaling) relationships. Effective turbulence values are determined from the portion of the vertical profile of lateral turbulence between the plume height and the receptor height. The effective lateral turbulence is then used to estimate horizontal dispersion.



#### k. Vertical Dispersion

In the stable boundary layer, Gaussian vertical dispersion coefficients are estimated as continuous functions of parameterized vertical turbulence. In the convective boundary layer, vertical dispersion is characterized by a bi-Gaussian probability density function and is also estimated as a continuous function of parameterized vertical turbulence. Vertical turbulence profiles are developed from measurements and similarity (scaling) relationships. These turbulence profiles account for both convective and mechanical turbulence. Effective turbulence values are determined from the portion of the vertical profile of vertical turbulence between the plume height and the receptor height. The effective vertical turbulence is then used to estimate vertical dispersion.

#### l. Chemical Transformation

Chemical transformations are generally not treated by AERMOD. However, AERMOD does contain an option to treat chemical transformation using simple exponential decay, although this option is typically not used in regulatory applications except for sources of sulfur dioxide in urban areas. Either a decay coefficient or a half-life is input by the user. Note also that the Plume Volume Molar Ratio Method and the Ozone Limiting Method (section 4.2.3.4) for NO<sub>2</sub> analyses are available.

#### m. Physical Removal

AERMOD can be used to treat dry and wet deposition for both gases and particles.

#### n. Evaluation Studies

American Petroleum Institute, 1998.

Evaluation of State of the Science of Air Quality Dispersion Model, Scientific Evaluation, prepared by Woodward-Clyde Consultants, Lexington, Massachusetts, for American Petroleum Institute, Washington, DC 20005-4070.

Brode, R.W., 2002. Implementation and Evaluation of PRIME in AERMOD. Preprints of the 12th Joint Conference on Applications of Air Pollution Meteorology, May 20-24, 2002; American Meteorological Society, Boston, MA.

Brode, R.W., 2004. Implementation and Evaluation of Bulk Richardson Number Scheme in AERMOD. 13th Joint Conference on Applications of Air Pollution Meteorology, August 23-26, 2004; American Meteorological Society, Boston, MA.

U.S. Environmental Protection Agency, 2003. AERMOD: Latest Features and Evaluation Results. Publication No. EPA-454/R-03-003. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

Heist, D., et al, 2013. Estimating near-road pollutant dispersion: A model inter-comparison. *Transportation Research Part D: Transport and Environment*, 25: pp 93-105.

#### A.2 CTDMPPLUS (Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations)

##### References

- Perry, S.G., D.J. Burns, L.H. Adams, R.J. Paine, M.G. Dennis, M.T. Mills, D.G. Strimaitis, R.J. Yamartino and E.M. Insley, 1989. User's Guide to the Complex Terrain Dispersion Model Plus Algorithms for Unstable Situations (CTDMPLUS). Volume 1: Model Descriptions and User Instructions. EPA Publication No. EPA-600/8-89-041. U.S. Environmental Protection Agency, Research Triangle Park, NC. (NTIS No. PB 89-181424).
- Perry, S.G., 1992. CTDMPPLUS: A Dispersion Model for Sources near Complex Topography. Part I: Technical Formulations. *Journal of Applied Meteorology*, 31(7): 633-645.

##### Availability

The model codes and associated documentation are available on the EPA's SCRAM Web site (paragraph A.0(3)).

##### Abstract

CTDMPLUS is a refined point source Gaussian air quality model for use in all stability conditions for complex terrain applications. The model contains, in its entirety, the technology of CTDMP for stable and neutral conditions. However, CTDMPPLUS can also simulate daytime, unstable conditions, and has a number of additional capabilities for improved user friendliness. Its use of meteorological data and terrain information is different from other EPA models; considerable detail for both types of input data is required and is supplied by preprocessors specifically designed for CTDMPPLUS. CTDMPPLUS requires the parameterization of individual hill shapes using the terrain preprocessor and the association of each model receptor with a particular hill.

##### a. Regulatory Use

CTDMPLUS is appropriate for the following applications:

- Elevated point sources;
- Terrain elevations above stack top;
- Rural or urban areas;
- Transport distances less than 50 kilometers; and
- 1-hour to annual averaging times when used with a post-processor program such as CHAVG.

##### b. Input Requirements

(1) Source data: For each source, user supplies source location, height, stack diameter, stack exit velocity, stack exit temperature, and emission rate; if variable emissions are appropriate, the user supplies hourly values for emission rate, stack exit velocity, and stack exit temperature.

(2) Meteorological data: For applications of CTDMPPLUS, multiple level (typically three or more) measurements of wind speed and direction, temperature and turbulence (wind fluctuation statistics) are required to create the basic meteorological data file ("PROFILE"). Such measurements should be obtained up to the representative plume

height(s) of interest (*i.e.*, the plume height(s) under those conditions important to the determination of the design concentration). The representative plume height(s) of interest should be determined using an appropriate complex terrain screening procedure (*e.g.*, CTSCREEN) and should be documented in the monitoring/modeling protocol. The necessary meteorological measurements should be obtained from an appropriately sited meteorological tower augmented by SODAR and/or RASS if the representative plume height(s) of interest is above the levels represented by the tower measurements. Meteorological preprocessors then create a SURFACE data file (hourly values of mixed layer heights, surface friction velocity, Monin-Obukhov length and surface roughness length) and a RAWINSONDE data file (upper air measurements of pressure, temperature, wind direction, and wind speed).

(3) Receptor data: Receptor names (up to 400) and coordinates, and hill number (each receptor must have a hill number assigned).

(4) Terrain data: User inputs digitized contour information to the terrain preprocessor which creates the TERRAIN data file (for up to 25 hills).

##### c. Output

(1) When CTDMPPLUS is run, it produces a concentration file, in either binary or text format (user's choice), and a list file containing a verification of model inputs, *i.e.*,

- Input meteorological data from "SURFACE" and "PROFILE,"
- Stack data for each source,
- Terrain information,
- Receptor information, and
- Source-receptor location (line printer map).

(2) In addition, if the case-study option is selected, the listing includes:

- Meteorological variables at plume height,
- Geometrical relationships between the source and the hill, and
- Plume characteristics at each receptor, *i.e.*,

—Distance in along-flow and cross flow direction

—Effective plume-receptor height difference

—Effective  $\sigma_y$  &  $\sigma_z$  values, both flat terrain and hill induced (the difference shows the effect of the hill)

—Concentration components due to WRAP, LIFT and FLAT.

(3) If the user selects the TOPN option, a summary table of the top four concentrations at each receptor is given. If the ISOR option is selected, a source contribution table for every hour will be printed.

(4) A separate output file of predicted (1-hour only) concentrations ("CONC") is written if the user chooses this option. Three forms of output are possible:

- (i) A binary file of concentrations, one value for each receptor in the hourly sequence as run;
- (ii) A text file of concentrations, one value for each receptor in the hourly sequence as run; or
- (iii) A text file as described above, but with a listing of receptor information (names, positions, hill number) at the beginning of the file.

(5) Hourly information provided to these files besides the concentrations themselves includes the year, month, day, and hour information as well as the receptor number with the highest concentration.

#### d. Type of Model

CTDMPLUS is a refined steady-state, point source plume model for use in all stability conditions for complex terrain applications.

#### e. Pollutant Types

CTDMPLUS may be used to model non-reactive, primary pollutants.

#### f. Source-Receptor Relationship

Up to 40 point sources, 400 receptors and 25 hills may be used. Receptors and sources are allowed at any location. Hill slopes are assumed not to exceed 15°, so that the linearized equation of motion for Boussinesq flow are applicable. Receptors upwind of the impingement point, or those associated with any of the hills in the modeling domain, require separate treatment.

#### g. Plume Behavior

(1) As in CTDM, the basic plume rise algorithms are based on Briggs' (1975) recommendations.

(2) A central feature of CTDMPLUS for neutral/stable conditions is its use of a critical dividing-streamline height ( $H_c$ ) to separate the flow in the vicinity of a hill into two separate layers. The plume component in the upper layer has sufficient kinetic energy to pass over the top of the hill while streamlines in the lower portion are constrained to flow in a horizontal plane around the hill. Two separate components of CTDMPLUS compute ground-level concentrations resulting from plume material in each of these flows.

(3) The model calculates on an hourly (or appropriate steady averaging period) basis how the plume trajectory (and, in stable/neutral conditions, the shape) is deformed by each hill. Hourly profiles of wind and temperature measurements are used by CTDMPLUS to compute plume rise, plume penetration (a formulation is included to handle penetration into elevated stable layers, based on Briggs (1984)), convective scaling parameters, the value of  $H_c$ , and the Froude number above  $H_c$ .

#### h. Horizontal Winds

CTDMPLUS does not simulate calm meteorological conditions. Both scalar and vector wind speed observations can be read by the model. If vector wind speed is unavailable, it is calculated from the scalar wind speed. The assignment of wind speed (either vector or scalar) at plume height is done by either:

- Interpolating between observations above and below the plume height, or
- Extrapolating (within the surface layer) from the nearest measurement height to the plume height.

#### i. Vertical Wind Speed

Vertical flow is treated for the plume component above the critical dividing streamline height ( $H_c$ ); see "Plume Behavior."

#### j. Horizontal Dispersion

Horizontal dispersion for stable/neutral conditions is related to the turbulence velocity scale for lateral fluctuations,  $\sigma_v$ , for which a minimum value of 0.2 m/s is used. Convective scaling formulations are used to estimate horizontal dispersion for unstable conditions.

#### k. Vertical Dispersion

Direct estimates of vertical dispersion for stable/neutral conditions are based on observed vertical turbulence intensity, *e.g.*,  $\sigma_w$  (standard deviation of the vertical velocity fluctuation). In simulating unstable (convective) conditions, CTDMPLUS relies on a skewed, bi-Gaussian probability density function (pdf) description of the vertical velocities to estimate the vertical distribution of pollutant concentration.

#### l. Chemical Transformation

Chemical transformation is not treated by CTDMPLUS.

#### m. Physical Removal

Physical removal is not treated by CTDMPLUS (complete reflection at the ground/hill surface is assumed).

#### n. Evaluation Studies

Burns, D.J., L.H. Adams and S.G. Perry, 1990. Testing and Evaluation of the CTDMPLUS Dispersion Model: Daytime Convective Conditions. U.S. Environmental Protection Agency, Research Triangle Park, NC.

Paumier, J.O., S.G. Perry and D.J. Burns, 1990. An Analysis of CTDMPLUS Model Predictions with the Lovett Power Plant Data Base. U.S. Environmental Protection Agency, Research Triangle Park, NC.

Paumier, J.O., S.G. Perry and D.J. Burns, 1992. CTDMPLUS: A Dispersion Model for Sources near Complex Topography. Part II: Performance Characteristics. *Journal of Applied Meteorology*, 31(7): 646-660.

### A.3 OCD (Offshore and Coastal Dispersion Model)

#### Reference

DiCristofaro, D.C. and S.R. Hanna, 1989. OCD: The Offshore and Coastal Dispersion Model, Version 4. Volume I: User's Guide, and Volume II: Appendices. Sigma Research Corporation, Westford, MA. (NTIS Nos. PB 93-144384 and PB 93-144392).

#### Availability

The model codes and associated documentation are available on EPA's SCRAM Web site (paragraph A.0(3)).

#### Abstract

(1) OCD is a straight-line Gaussian model developed to determine the impact of offshore emissions from point, area or line sources on the air quality of coastal regions. OCD incorporates overwater plume transport and dispersion as well as changes that occur as the plume crosses the shoreline. Hourly meteorological data are needed from both offshore and onshore locations. These include water surface temperature, overwater

air temperature, mixing height, and relative humidity.

(2) Some of the key features include platform building downwash, partial plume penetration into elevated inversions, direct use of turbulence intensities for plume dispersion, interaction with the overland internal boundary layer, and continuous shoreline fumigation.

#### a. Regulatory Use

OCD has been recommended for use by the Bureau of Ocean Energy Management for emissions located on the Outer Continental Shelf (50 FR 12248; 28 March 1985). OCD is applicable for overwater sources where onshore receptors are below the lowest source height. Where onshore receptors are above the lowest source height, offshore plume transport and dispersion may be modeled on a case-by-case basis in consultation with the appropriate reviewing authority (paragraph 3.0(b)).

#### b. Input Requirements

(1) Source data: Point, area or line source location, pollutant emission rate, building height, stack height, stack gas temperature, stack inside diameter, stack gas exit velocity, stack angle from vertical, elevation of stack base above water surface and gridded specification of the land/water surfaces. As an option, emission rate, stack gas exit velocity and temperature can be varied hourly.

(2) Meteorological data: PCRAMMET is the recommended meteorological data preprocessor for use in applications of OCD employing hourly NWS data. MPRM is the recommended meteorological data preprocessor for applications of OCD employing site-specific meteorological data.

(i) Over land: Surface weather data including hourly stability class, wind direction, wind speed, ambient temperature, and mixing height are required.

(ii) Over water: Hourly values for mixing height, relative humidity, air temperature, and water surface temperature are required; if wind speed/direction are missing, values over land will be used (if available); vertical wind direction shear, vertical temperature gradient, and turbulence intensities are optional.

(3) Receptor data: Location, height above local ground-level, ground-level elevation above the water surface.

#### c. Output

(1) All input options, specification of sources, receptors and land/water map including locations of sources and receptors.

(2) Summary tables of five highest concentrations at each receptor for each averaging period, and average concentration for entire run period at each receptor.

(3) Optional case study printout with hourly plume and receptor characteristics. Optional table of annual impact assessment from non-permanent activities.

(4) Concentration output files can be used by ANALYSIS postprocessor to produce the highest concentrations for each receptor, the cumulative frequency distributions for each receptor, the tabulation of all concentrations exceeding a given threshold, and the manipulation of hourly concentration files.

#### d. Type of Model

OCD is a Gaussian plume model constructed on the framework of the MPTER model.

#### e. Pollutant Types

OCD may be used to model primary pollutants. Settling and deposition are not treated.

#### f. Source-Receptor Relationship

(1) Up to 250 point sources, 5 area sources, or 1 line source and 180 receptors may be used.

(2) Receptors and sources are allowed at any location.

(3) The coastal configuration is determined by a grid of up to 3600 rectangles. Each element of the grid is designated as either land or water to identify the coastline.

#### g. Plume Behavior

(1) The basic plume rise algorithms are based on Briggs' recommendations.

(2) Momentum rise includes consideration of the stack angle from the vertical.

(3) The effect of drilling platforms, ships, or any overwater obstructions near the source are used to decrease plume rise using a revised platform downwash algorithm based on laboratory experiments.

(4) Partial plume penetration of elevated inversions is included using the suggestions of Briggs (1975) and Weil and Brower (1984).

(5) Continuous shoreline fumigation is parameterized using the Turner method where complete vertical mixing through the thermal internal boundary layer (TIBL) occurs as soon as the plume intercepts the TIBL.

#### h. Horizontal Winds

(1) Constant, uniform wind is assumed for each hour.

(2) Overwater wind speed can be estimated from overland wind speed using relationship of Hsu (1981).

(3) Wind speed profiles are estimated using similarity theory (Businger, 1973). Surface layer fluxes for these formulas are calculated from bulk aerodynamic methods.

#### i. Vertical Wind Speed

Vertical wind speed is assumed equal to zero.

#### j. Horizontal Dispersion

(1) Lateral turbulence intensity is recommended as a direct estimate of horizontal dispersion. If lateral turbulence intensity is not available, it is estimated from boundary layer theory. For wind speeds less than 8 m/s, lateral turbulence intensity is assumed inversely proportional to wind speed.

(2) Horizontal dispersion may be enhanced because of obstructions near the source. A virtual source technique is used to simulate the initial plume dilution due to downwash.

(3) Formulas recommended by Pasquill (1976) are used to calculate buoyant plume enhancement and wind direction shear enhancement.

(4) At the water/land interface, the change to overland dispersion rates is modeled using a virtual source. The overland dispersion rates can be calculated from either lateral turbulence intensity or Pasquill-Gifford curves. The change is implemented where the plume intercepts the rising internal boundary layer.

#### k. Vertical Dispersion

(1) Observed vertical turbulence intensity is not recommended as a direct estimate of vertical dispersion. Turbulence intensity should be estimated from boundary layer theory as default in the model. For very stable conditions, vertical dispersion is also a function of lapse rate.

(2) Vertical dispersion may be enhanced because of obstructions near the source. A virtual source technique is used to simulate the initial plume dilution due to downwash.

(3) Formulas recommended by Pasquill (1976) are used to calculate buoyant plume enhancement.

(4) At the water/land interface, the change to overland dispersion rates is modeled using a virtual source. The overland dispersion rates can be calculated from either vertical turbulence intensity or the Pasquill-Gifford coefficients. The change is implemented where the plume intercepts the rising internal boundary layer.

#### l. Chemical Transformation

Chemical transformations are treated using exponential decay. Different rates can be specified by month and by day or night.

#### m. Physical Removal

Physical removal is also treated using exponential decay.

#### n. Evaluation Studies

DiCristofaro, D.C. and S.R. Hanna, 1989. OCD: The Offshore and Coastal Dispersion Model. Volume I: User's Guide. Sigma Research Corporation, Westford, MA.

Hanna, S.R., L.L. Schulman, R.J. Paine and J.E. Pleim, 1984. The Offshore and Coastal Dispersion (OCD) Model User's Guide, Revised. OCS Study, MMS 84-0069. Environmental Research & Technology, Inc., Concord, MA. (NTIS No. PB 86-159803).

Hanna, S.R., L.L. Schulman, R.J. Paine, J.E. Pleim and M. Baer, 1985. Development and Evaluation of the Offshore and Coastal Dispersion (OCD) Model. *Journal of the Air Pollution Control Association*, 35: 1039-1047.

Hanna, S.R. and D.C. DiCristofaro, 1988. Development and Evaluation of the OCD/API Model. Final Report, API Pub. 4461, American Petroleum Institute, Washington, DC.

[FR Doc. 2016-31747 Filed 1-13-17; 8:45 am]

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# FEDERAL REGISTER

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Part V

Department of Homeland Security

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8 CFR Parts 103, 212, and 274a  
International Entrepreneur Rule; Final Rule

## DEPARTMENT OF HOMELAND SECURITY

### 8 CFR Parts 103, 212, and 274a

[CIS No. 2572–15; DHS Docket No. USCIS–2015–0006]

RIN 1615–AC04

#### International Entrepreneur Rule

**AGENCY:** U.S. Citizenship and Immigration Services, DHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends Department of Homeland Security (DHS) regulations to implement the Secretary of Homeland Security's discretionary parole authority in order to increase and enhance entrepreneurship, innovation, and job creation in the United States. The final rule adds new regulatory provisions guiding the use of parole on a case-by-case basis with respect to entrepreneurs of start-up entities who can demonstrate through evidence of substantial and demonstrated potential for rapid business growth and job creation that they would provide a significant public benefit to the United States. Such potential would be indicated by, among other things, the receipt of significant capital investment from U.S. investors with established records of successful investments, or obtaining significant awards or grants from certain Federal, State or local government entities. If granted, parole would provide a temporary initial stay of up to 30 months (which may be extended by up to an additional 30 months) to facilitate the applicant's ability to oversee and grow his or her start-up entity in the United States.

**DATES:** This final rule is effective July 17, 2017.

**FOR FURTHER INFORMATION CONTACT:** Steven Viger, Adjudications Officer, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Suite 1100, Washington, DC 20529–2140; Telephone (202) 272–1470.

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Executive Summary
  - A. Purpose of the Regulatory Action
  - B. Legal Authority
  - C. Summary of the Final Rule Provisions
  - D. Summary of Changes From the Notice of Proposed Rulemaking
  - E. Summary of Costs and Benefits
  - F. Effective Date
- II. Background
  - A. Current Framework
  - B. Final Rule

- III. Public Comments on Proposed Rule
  - A. Summary of Public Comments
  - B. Legal Authority
  - C. Significant Public Benefit
  - D. Definitions
  - E. Application Requirements
  - F. Parole Criteria and Conditions
  - G. Employment Authorization
  - H. Comments on Parole Process
  - I. Appeals and Motions To Reopen
  - J. Termination of Parole
  - K. Opposition to the Overall Rule
  - L. Miscellaneous Comments on the Rule
  - M. Public Comments on Statutory and Regulatory Requirements
- IV. Statutory and Regulatory Requirements
  - A. Unfunded Mandates Reform Act of 1995
  - B. Small Business Regulatory Enforcement Fairness Act of 1996
  - C. Executive Orders 12866 and 13563
    - 1. Summary
    - 2. Purpose of the Rule
    - 3. Volume Estimate
    - 4. Costs
    - 5. Benefits
    - 6. Alternatives Considered
  - D. Regulatory Flexibility Act
  - E. Executive Order 13132
  - F. Executive Order 12988
  - G. Paperwork Reduction Act

#### I. Executive Summary

##### A. Purpose of the Regulatory Action

Section 212(d)(5) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(5), confers upon the Secretary of Homeland Security the discretionary authority to parole individuals into the United States temporarily, on a case-by-case basis, for urgent humanitarian reasons or significant public benefit. DHS is amending its regulations implementing this authority to increase and enhance entrepreneurship, innovation, and job creation in the United States. As described in more detail below, the final rule would establish general criteria for the use of parole with respect to entrepreneurs of start-up entities who can demonstrate through evidence of substantial and demonstrated potential for rapid growth and job creation that they would provide a significant public benefit to the United States. In all cases, whether to parole a particular individual under this rule is a discretionary determination that would be made on a case-by-case basis.

Given the complexities involved in adjudicating applications in this context, DHS has decided to establish by regulation the criteria for the case-by-case evaluation of parole applications filed by entrepreneurs of start-up entities. By including such criteria in regulation, as well as establishing application requirements that are specifically tailored to capture the necessary information for processing parole requests on this basis, DHS

expects to facilitate the use of parole in this area.

Under this final rule, an applicant would need to demonstrate that his or her parole would provide a significant public benefit because he or she is the entrepreneur of a new start-up entity in the United States that has significant potential for rapid growth and job creation. DHS believes that such potential would be indicated by, among other things, the receipt of (1) significant capital investment from U.S. investors with established records of successful investments or (2) significant awards or grants from certain Federal, State, or local government entities. The final rule also includes alternative criteria for applicants who partially meet the thresholds for capital investment or government awards or grants and can provide additional reliable and compelling evidence of their entities' significant potential for rapid growth and job creation. An applicant must also show that he or she has a substantial ownership interest in such an entity, has an active and central role in the entity's operations, and would substantially further the entity's ability to engage in research and development or otherwise conduct and grow its business in the United States. The grant of parole is intended to facilitate the applicant's ability to oversee and grow the start-up entity.

DHS believes that this final rule will encourage foreign entrepreneurs to create and develop start-up entities with high growth potential in the United States, which are expected to facilitate research and development in the country, create jobs for U.S. workers, and otherwise benefit the U.S. economy through increased business activity, innovation, and dynamism. Particularly in light of the complex considerations involved in entrepreneur-based parole requests, DHS also believes that this final rule will provide a transparent framework by which DHS will exercise its discretion to adjudicate such requests on a case-by-case basis under section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5).

##### B. Legal Authority

The Secretary of Homeland Security's authority for the proposed regulatory amendments can be found in various provisions of the immigration laws. Sections 103(a)(1) and (3) of the INA, 8 U.S.C. 1103(a)(1), (3), provides the Secretary the authority to administer and enforce the immigration and nationality laws. Section 402(4) of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 202(4), expressly authorizes the

Secretary to establish rules and regulations governing parole. Section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5), vests in the Secretary the discretionary authority to grant parole for urgent humanitarian reasons or significant public benefit to applicants for admission temporarily on a case-by-case basis.<sup>1</sup> Section 274A(h)(3)(B) of the INA, 8 U.S.C. 1324a(h)(3)(B), recognizes the Secretary's general authority to extend employment authorization to noncitizens in the United States. And section 101(b)(1)(F) of the HSA, 6 U.S.C. 111(b)(1)(F), establishes as a primary mission of DHS the duty to "ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland."

### C. Summary of the Final Rule Provisions

This final rule adds a new section 8 CFR 212.19 to provide guidance with respect to the use of parole for entrepreneurs of start-up entities based upon significant public benefit. An individual seeking to operate and grow his or her start-up entity in the United States would generally need to demonstrate the following to be considered for a discretionary grant of parole under this final rule:

1. *Formation of New Start-Up Entity.* The applicant has recently formed a new entity in the United States that has lawfully done business since its creation and has substantial potential for rapid growth and job creation. An entity may be considered recently formed if it was created within the 5 years immediately preceding the date of the filing of the initial parole application. See 8 CFR 219.12(a)(2), 8 CFR 103.2(a)(7).

2. *Applicant is an Entrepreneur.* The applicant is an entrepreneur of the start-up entity who is well-positioned to advance the entity's business. An applicant may meet this standard by providing evidence that he or she: (1) Possesses a significant (at least 10 percent) ownership interest in the entity at the time of adjudication of the initial

grant of parole; and (2) has an active and central role in the operations and future growth of the entity, such that his or her knowledge, skills, or experience would substantially assist the entity in conducting and growing its business in the United States. See final 8 CFR 212.19(a)(1). Such an applicant cannot be a mere investor.

3. *Significant U.S. Capital Investment or Government Funding.* The applicant can further validate, through reliable supporting evidence, the entity's substantial potential for rapid growth and job creation. An applicant may be able to satisfy this criterion in one of several ways:

a. *Investments from established U.S. investors.* The applicant may show that the entity has received significant investment of capital from certain qualified U.S. investors with established records of successful investments. An applicant would generally be able to meet this standard by demonstrating that the start-up entity has received investments of capital totaling \$250,000 or more from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities.

b. *Government grants.* The applicant may show that the start-up entity has received significant awards or grants from Federal, State or local government entities with expertise in economic development, research and development, or job creation. An applicant would generally be able to meet this standard by demonstrating that the start-up entity has received monetary awards or grants totaling \$100,000 or more from government entities that typically provide such funding to U.S. businesses for economic, research and development, or job creation purposes.

c. *Alternative criteria.* The final rule provides alternative criteria under which an applicant who partially meets one or more of the above criteria related to capital investment or government funding may be considered for parole under this rule if he or she provides additional reliable and compelling evidence that they would provide a significant public benefit to the United States. Such evidence must serve as a compelling validation of the entity's substantial potential for rapid growth and job creation.

This final rule states that an applicant who meets the above criteria (and his or her spouse and minor, unmarried children,<sup>2</sup> if any) generally may be

considered under this rule for a discretionary grant of parole lasting up to 30 months (2.5 years) based on the significant public benefit that would be provided by the applicant's (or family's) parole into the United States. An applicant will be required to file a new application specifically tailored for entrepreneurs to demonstrate eligibility for parole based upon significant public benefit under this rule, along with applicable fees. Applicants will also be required to appear for collection of biometric information. No more than three entrepreneurs may receive parole with respect to any one qualifying start-up entity.

USCIS adjudicators will consider the totality of the evidence, including evidence obtained by USCIS through background checks and other means, to determine whether the applicant has satisfied the above criteria, whether the specific applicant's parole would provide a significant public benefit, and whether negative factors exist that warrant denial of parole as a matter of discretion. To grant parole, adjudicators will be required to conclude, based on the totality of the circumstances, that both: (1) The applicant's parole would provide a significant public benefit, and (2) the applicant merits a grant of parole as a matter of discretion.

If parole is granted, the entrepreneur will be authorized for employment incident to the grant of parole, but only with respect to the entrepreneur's start-up entity. The entrepreneur's spouse and children, if any, will not be authorized for employment incident to the grant of parole, but the entrepreneur's spouse, if paroled into the United States pursuant to 8 CFR 212.19, will be permitted to apply for employment authorization consistent with new 8 CFR 274a.12(c)(34). DHS retains the authority to revoke any such grant of parole at any time as a matter of discretion or if DHS determines that parole no longer provides a significant public benefit, such as when the entity has ceased operations in the United States or DHS has reason to believe that the approved application involves fraud or misrepresentation. See new 8 CFR 212.19(k).

As noted, the purpose of this parole process is to provide qualified entrepreneurs of high-potential start-up entities in the United States with the improved ability to conduct research and development and expand the entities' operations in the United States so that our nation's economy may

<sup>1</sup>In sections 402 and 451 of the HSA, Congress transferred from the Attorney General to the Secretary of Homeland Security the general authority to enforce and administer the immigration laws, including those pertaining to parole. In accordance with section 1517 of title XV of the HSA, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS "shall be deemed to refer to the Secretary" of Homeland Security. See 6 U.S.C. 557 (codifying the HSA, tit. XV, section 1517). Authorities and functions of DHS to administer and enforce the immigration laws are appropriately delegated to DHS employees and others in accordance with section 102(b)(1) of the HSA, 6 U.S.C. 112(b)(1); section 103(a) of the INA, 8 U.S.C. 1103(a); and 8 CFR 2.1.

<sup>2</sup>The terms "child" and "children" in this proposed rule have the same meaning as they do

under section 101(b)(1) of the INA, 8 U.S.C. 1101(b)(1) (defining a child as one who is unmarried and under twenty-one years of age).

benefit from such development and expansion, including through increased capital expenditures, innovation, and job creation. The final rule allows individuals granted parole under this rule to be considered for re-parole for an additional period of up to 30 months (2.5 years) if, and only if, they can demonstrate that their entities have shown signs of significant growth since the initial grant of parole and such entities continue to have substantial potential for rapid growth and job creation.

An applicant under this rule will generally need to demonstrate the following to be considered for a discretionary grant of an additional period of parole:

1. *Continuation of Start-Up Entity.* The entity continues to be a start-up entity as defined by the proposed rule. For purposes of seeking re-parole, an applicant may be able to meet this standard by showing that the entity: (a) Has been lawfully operating in the United States during the period of parole; and (b) continues to have substantial potential for rapid growth and job creation.

2. *Applicant Continues to Be an Entrepreneur.* The applicant continues to be an entrepreneur of the start-up entity who is well-positioned to advance the entity's business. An applicant may meet this standard by providing evidence that he or she: (a) Continues to possess a significant (at least 5 percent) ownership interest in the entity at the time of adjudication of the grant of re-parole; and (b) continues to have an active and central role in the operations and future growth of the entity, such that his or her knowledge, skills, or experience would substantially assist the entity in conducting and continuing to grow its business in the United States. This reduced ownership amount takes into account the need of some successful start-up entities to raise additional venture capital investment by selling ownership interest during their initial years of operation.

3. *Significant U.S. Investment/Revenue/Job Creation.* The applicant further validates, through reliable supporting evidence, the start-up entity's continued potential for rapid growth and job creation. An applicant may be able to satisfy this criterion in one of several ways:

a. *Additional Investments or Grants.* The applicant may show that during the initial period of parole the start-up entity received additional substantial investments of capital, including through qualified investments from U.S. investors with established records of successful investments; significant

awards or grants from U.S. government entities that regularly provide such funding to start-up entities; or a combination of both. An applicant would generally be expected to demonstrate that the entity received at least \$500,000 in additional qualifying funding during the initial parole period. As noted previously, any private investment that the applicant is relying upon as evidence that the investment criterion has been met must be made by qualified U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities. Government awards or grants must be from U.S. federal, state or local government entities with expertise in economic development, research and development, or job creation.

b. *Revenue generation.* The applicant may show that the start-up entity has generated substantial and rapidly increasing revenue in the United States during the initial parole period. To satisfy this criterion, an applicant will need to demonstrate that the entity reached at least \$500,000 in annual revenue, with average annualized revenue growth of at least 20 percent, during the initial parole period.

c. *Job creation.* The applicant may show that the start-up entity has demonstrated substantial job creation in the United States during the initial parole period. To satisfy this criterion, an applicant will need to demonstrate that the entity created at least 5 full-time jobs for U.S. workers during the initial parole period.

d. *Alternative criteria.* As with initial parole, the final rule includes alternative criteria under which an applicant who partially meets one or more of the above criteria related to capital investment, revenue generation, or job creation may be considered for re-parole under this rule if he or she provides additional reliable and compelling evidence that his or her parole will continue to provide a significant public benefit. As discussed above, such evidence must serve as a compelling validation of the entity's substantial potential for rapid growth and job creation.

As indicated above, an applicant who generally meets the above criteria and merits a favorable exercise of discretion may be granted an additional 30-month period of re-parole, for a total maximum period of 5 years of parole under 8 CFR 212.19, to work with the same start-up entity based on the significant public benefit that would be served by his or her continued parole in the United States. No more than three

entrepreneurs (and their spouses and children) may receive such additional periods of parole with respect to any one qualifying entity.

As with initial parole applications, USCIS adjudicators will consider the totality of the evidence, including evidence obtained by USCIS through verification methods, to determine whether the applicant has satisfied the above criteria and whether his or her continued parole would provide a significant public benefit. To be re-paroled, adjudicators will be required to conclude, based on the totality of the circumstances, both: (1) That the applicant's continued parole would provide a significant public benefit, and (2) that the applicant continues to merit parole as a matter of discretion. If the applicant is re-paroled, DHS retains the authority to revoke parole at any time as a matter of discretion or if DHS determines that parole no longer provides a significant public benefit, such as when the entity has ceased operations in the United States or DHS believes that the application involved fraud or made material misrepresentations.

The entrepreneur and any dependents granted parole under this program will be required to depart the United States when their parole periods have expired or have otherwise been terminated, unless such individuals are otherwise eligible to lawfully remain in the United States. At any time prior to reaching the 5-year limit for parole under this final rule, such individuals may apply for any immigrant or nonimmigrant classification for which they may be eligible (such as classification as an O-1 nonimmigrant or as a lawful permanent resident pursuant to an EB-2 National Interest Waiver). Because parole is not considered an admission to the United States, parolees are ineligible to adjust or change their status in the United States under many immigrant or nonimmigrant visa classifications. For example, if such individuals are approved for a nonimmigrant or employment-based immigrant visa classification, they would generally need to depart the United States and apply for a visa with the Department of State (DOS) for admission to the United States as a nonimmigrant or lawful permanent resident.

Finally, DHS is making conforming changes to the employment authorization regulations at 8 CFR 274a.12(b) and (c), the employment eligibility verification regulations at 8 CFR 274a.2(b), and fee regulations at 8 CFR 103.7(b)(i). The final rule amends 8 CFR 274a.12(b) by: (1) Adding entrepreneur parolees to the classes of



aliens authorized for employment incident to their immigration status or parole, and (2) providing temporary employment authorization for those applying for re-parole. The final rule amends 8 CFR 274a.12(c) by extending eligibility for employment authorization to the spouse of an entrepreneur paroled into the United States under 8 CFR 212.19. The final rule amends 8 CFR 274a.2(b) by designating the entrepreneur's foreign passport and Arrival/Departure Record (Form I-94) indicating entrepreneur parole as acceptable evidence for employment eligibility verification (Form I-9) purposes.<sup>3</sup> The final rule also amends 8 CFR 103.7(b)(i) by including the fee for the new Application for Entrepreneur Parole form.

#### *D. Summary of Changes From the Notice of Proposed Rulemaking*

Following careful consideration of public comments received, including relevant data provided by stakeholders, DHS has made several modifications to the regulatory text proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on August 31, 2016. See 81 FR 60129. Those changes include the following:

- **Minimum Investment Amount.** In the final rule, DHS is responding to public comment by revising proposed 8 CFR 212.19(b)(2)(ii)(B)(1), a provision that identifies the qualifying investment amount required from one or more qualified investors. In the NPRM, DHS proposed a minimum investment amount of \$345,000. Based on data provided by the public, DHS is revising this figure to \$250,000. Thus, under the final rule, an applicant would generally be able to meet the investment standard by demonstrating that the start-up entity has received investments of capital totaling \$250,000 or more from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities. In addition, DHS has increased the timeframe during which the qualifying investments must be received from 365 days to 18 months immediately preceding the filing of an application for initial parole.

- **Definition of Entrepreneur: Ownership Criteria.** In the final rule,

DHS is revising proposed 8 CFR 212.19(a)(1), a provision that defines the term "entrepreneur," and establishes a minimum ownership percentage necessary to meet the definition. In the NPRM, DHS proposed that the entrepreneur must have an ownership interest of at least 15 percent for initial parole, and 10 percent for re-parole. In response to public comment, DHS is modifying this requirement to allow individuals who have an ownership interest of at least 10 percent in the start-up entity at the time of adjudication of the initial grant of parole, and at least a 5 percent ownership interest at the time of adjudication of a subsequent period of re-parole, to qualify under this definition.

- **Qualified Investment Definition.** DHS is revising proposed 8 CFR 212.19(a)(4), which establishes the definition of a qualified investment. In the NPRM, DHS proposed that the term "qualified investment" means an investment made in good faith, and that is not an attempt to circumvent any limitations imposed on investments under this section, of lawfully derived capital in a start-up entity that is a purchase from such entity of equity or convertible debt issued by such entity. In response to public comment, DHS is modifying this definition to include other securities that are convertible into equity issued by such an entity and that are commonly used in financing transactions within such entity's industry.

- **Qualified Investor Definition.** DHS is revising proposed 8 CFR 212.19(a)(5), which establishes the definition of a qualified investor. In the NPRM, DHS proposed that an individual or organization may be considered a qualified investor if, during the preceding 5 years: (i) The individual or organization made investments in start-up entities in exchange for equity or convertible debt in at least 3 separate calendar years comprising a total within such 5-year period of no less than \$1,000,000; and (ii) subsequent to such investment by such individual or organization, at least 2 such entities each created at least 5 qualified jobs or generated at least \$500,000 in revenue with average annualized revenue growth of at least 20 percent. In this final rule, the minimum investment amount has been decreased from the originally proposed \$1,000,000 to \$600,000. The requirement that investments be made in at least 3 separate calendar years has also been removed from this final rule. DHS is also making revisions to the form of investment made by the individual or organization consistent

with the change to the qualified investment definition by adding "or other security convertible into equity commonly used in financing transactions within their respective industries."

- **Start-up Entity Definition.** In the final rule, DHS is revising the definition of a start-up entity as proposed in 8 CFR 212.19(a)(2). In the NPRM, DHS proposed that an entity may be considered recently formed if it was created within the 3 years preceding the date of filing of the initial parole request. In response to public comment, DHS is modifying this provision so that an entity may be considered recently formed if it was created within the 5 years immediately preceding the filing date of the initial parole request.

Additionally, for purposes of paragraphs (a)(3) and (a)(5) of this section, which pertain to the definitional requirements to be a qualified investor or qualified government award or grant, respectively, DHS made corresponding changes in this final rule such that an entity may be considered recently formed if it was created within the 5 years immediately preceding the receipt of the relevant grant(s), award(s), or investment(s).

- **Job Creation Requirement.** In the final rule, DHS is revising proposed 8 CFR 212.19(c)(2)(ii)(B)(2), a provision that identifies the minimum job creation requirement under the general re-parole criteria. In the NPRM, DHS proposed that an entrepreneur may be eligible for an additional period of parole by establishing that his or her start-up entity has created at least 10 qualified jobs during the initial parole period. In response to public comment, DHS is modifying this provision so that an entrepreneur may qualify for re-parole if the start-up entity created at least 5 qualified jobs with the start-up entity during the initial parole period.

- **Revenue Generation.** In the final rule, DHS is clarifying proposed 8 CFR 212.19(c)(2)(ii)(B)(3), a provision that identifies the minimum annual revenue requirement under the general re-parole criteria. DHS has clarified that for the revenue to be considered for purposes of re-parole, it must be generated in the United States.

- **Parole Validity Periods.** In the final rule, DHS is revising proposed 8 CFR 212.19(d)(2) and (3), which are provisions that identify the length of the initial and re-parole periods. In the NPRM, DHS proposed (1) a potential initial period of parole of up to 2 years beginning on the date the request is approved by USCIS and (2) a potential period of re-parole of up to 3 years beginning on the date of the expiration

<sup>3</sup> Additionally, DHS is making a technical change to this section by adding the Department of State (DOS) Consular Report of Birth Abroad (Form FS-240) to the regulatory text and to the "List C" listing of acceptable documents for Form I-9 verification purposes. This rule departs from the Notice of Proposed Rulemaking by not adding "or successor form" after Form FS-240. DHS determined that inclusion of the phrase is unnecessary and may cause confusion in the future.

of the initial parole period. First, DHS revised 8 CFR 212.19(d)(2) to correct that the initial parole period would begin running on the date the individual is initially paroled into the United States. Second, in response to public comment, DHS revised 8 CFR 212.19(d)(2) and (3) to provide 2 potential parole periods of up to 30 months each, rather than an initial 2-year period followed by a potential 3-year period of re-parole. Specifically, 8 CFR 212.19(d)(2) now provides that an applicant who meets the eligibility criteria (and his or her spouse and minor, unmarried children, if any) may be considered under this rule for a discretionary grant of an initial parole period of up to 30 months (2.5 years) based on the significant public benefit that would be provided by the applicant's (or family's) parole into the United States. DHS also revised in this final rule the period of re-parole in 8 CFR 212.19(d)(3) to reduce the period of re-parole from 3 years to 30 months in order to extend the initial parole period, while still maintaining the overall 5-year period of parole limitation.

- **Material Changes.** In the final rule, DHS is revising proposed 8 CFR 212.19(a)(10), a provision that defines material changes. The final rule adds the following to the definition of material changes: "a significant change with respect to ownership and control of the start-up entity." This reflects a change from the originally proposed language of any significant change to the entrepreneur's role in or ownership and control in the start-up entity or any other significant change with respect to ownership and control of the start-up entity. Additionally, the final rule at 8 CFR 212.19(a)(1) adds language that permits the entrepreneur during the initial parole period to reduce his or her ownership interest, as long as at least 5 percent ownership is maintained. This provision was revised in response to a number of public comments that requested that DHS reconsider how and when material changes should be reported.

- **Reporting of Material Changes.** In the final rule, DHS is revising proposed 8 CFR 212.19(j), a provision that describes reporting of material changes. DHS is revising 8 CFR 212.19(j) to allow DHS to provide additional flexibility in the future with respect to the manner in which material changes are reported to DHS. The final rule also makes conforming changes based on changes to the definition of entrepreneur.

- **Termination of Parole.** In the final rule, DHS is revising proposed 8 CFR 212.19(k)(2), a provision that describes automatic termination of parole. The

final rule makes conforming revisions to this provision based on changes to the definition of entrepreneur and to the material change provisions.

#### E. Summary of Costs and Benefits

DHS does not anticipate that this rule will generate significant costs and burdens to private or public entities. Costs of the rule stem from filing fees and opportunity costs associated with applying for parole, and the requirement that the entrepreneur notify DHS of any material changes.

DHS estimates that 2,940 entrepreneurs will be eligible for parole annually and can apply using the Application for Entrepreneur Parole (Form I-941). Each applicant for parole will face a total filing cost—including the application form fee, biometric filing fee, travel costs, and associated opportunity costs—of \$1,591, resulting in a total cost of \$4,678,336 (undiscounted) for the first full year the rule will take effect and any subsequent year. Additionally, dependent family members (spouses and children) seeking parole with the principal applicant will be required to file an Application for Travel Document (Form I-131) and submit biographical information and biometrics. DHS estimates approximately 3,234 dependent spouses and children could seek parole based on the estimate of 2,940 principal applicants. Each spouse and child 14 years of age and older seeking parole will face a total cost of \$765 per applicant,<sup>4</sup> for a total aggregate cost of \$2,474,914.<sup>5</sup> Additionally, spouses who apply for work authorization via an Application for Employment Authorization (Form I-765) will incur a total additional cost of \$446 each. Based on the same number of entrepreneurs, the estimated 2,940 spouses<sup>6</sup> will incur total costs of \$1,311,830 (undiscounted). The total cost of the rule to include direct filing costs and monetized non-

<sup>4</sup> On October 24, 2016, U.S. Citizenship and Immigration Services published a final rule establishing a new fee schedule for immigration benefits and services (81 FR 73292). The new filing fees for Form I-131 and Form I-765, \$575 and \$410, respectively, will be effective on December 23, 2016. This final rule uses those new filing fees in estimating costs to potential applicants under this rule.

<sup>5</sup> For parole requests for children under the age of 14, only the filing fee will be required, as such children do not appear for biometric collection. Applicants under the age of 14 and over the age of 79 are not required to be fingerprinted. However, they may still be required to attend a biometrics appointment in order to have their photographs and signatures captured.

<sup>6</sup> DHS used a simple one-to-one mapping of entrepreneurs to spouses to obtain 2,940 spouses, the same number as entrepreneur parolees.

filing costs is estimated to be \$8,136,571 annually.

DHS anticipates that establishing a parole process for those entrepreneurs who stand to provide a significant public benefit will advance the U.S. economy by enhancing innovation, generating capital investments, and creating jobs. DHS does not expect significant negative consequences or labor market impacts from this rule; indeed, DHS believes this rule will encourage entrepreneurs to pursue business opportunities in the United States rather than abroad, which can be expected to generate significant scientific, research and development, and technological impacts that could create new products and produce positive spillover effects to other businesses and sectors. The impacts stand to benefit the economy by supporting and strengthening high-growth, job-creating businesses in the United States.

#### F. Effective Date

This final rule will be effective on July 17, 2017, 180 days from the date of publication in the **Federal Register**. DHS has determined that this 180-day period is necessary to provide USCIS with a reasonable period to ensure resources are in place to process and adjudicate Applications for Entrepreneur Parole filed by eligible entrepreneurs and related applications filed by eligible dependents under this rule without sacrificing the quality of customer service for all USCIS stakeholders. USCIS believes it will thus be able to implement this rule in a manner that will avoid delays of processing these and other applications.

## II. Background

### A. Discretionary Parole Authority

The Secretary of Homeland Security has discretionary authority to parole into the United States temporarily "under conditions as he may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit any individual applying for admission to the United States," regardless of whether the alien is inadmissible. INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).<sup>7</sup> The Secretary's parole authority is expansive. Congress did not define the phrase "urgent humanitarian reasons or significant public benefit," entrusting interpretation and application of those

<sup>7</sup> Although section 212(d)(5) continues to refer to the Attorney General, the parole authority now resides exclusively with the Secretary of Homeland Security. See *Matter of Arrabally*, 25 I. & N. Dec. 771, 777 n.5 (BIA 2012).

standards to the Secretary. Aside from requiring case-by-case determinations, Congress limited the parole authority by restricting its use with respect to two classes of applicants for admissions: (1) Aliens who are refugees (unless the Secretary determines that “compelling reasons in the public interest with respect to that particular alien require that the alien be paroled . . . rather than be admitted as a refugee” under INA section 207, 8 U.S.C. 1157), *see* INA section 212(d)(5)(B), 8 U.S.C. 1182(d)(5)(B); and (2) certain alien crewmen during a labor dispute in specified circumstances (unless the Secretary “determines that the parole of such alien is necessary to protect the national security of the United States”), INA section 214(f)(2)(A), 8 U.S.C. 1184(f)(2)(A).

Parole decisions are discretionary determinations and must be made on a case-by-case basis consistent with the INA. To exercise its parole authority, DHS must determine that an individual’s parole into the United States is justified by urgent humanitarian reasons or significant public benefit. Even when one of those standards would be met, DHS may nevertheless deny parole as a matter of discretion based on other factors.<sup>8</sup> In making such discretionary determinations, USCIS considers all relevant information, including any criminal history or other serious adverse factors that would weigh against a favorable exercise of discretion.

Parole is not an admission to the United States. *See* INA sections 101(a)(13)(B), 212(d)(5)(A), 8 U.S.C. 1101(a)(13)(B), 1182(d)(5)(A); *see also* 8 CFR 1.2 (“An arriving alien remains an arriving alien even if paroled pursuant to section 212(d)(5) of the Act, and even after any such parole is terminated or revoked.”). Parole may also be terminated at any time in DHS’s discretion, consistent with existing regulations; in those cases, the individual is “restored to the status that he or she had at the time of parole.” 8 CFR 212.5(e); *see also* INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).<sup>9</sup>

DHS regulations at 8 CFR 212.5 generally describe DHS’s discretionary parole authority, including the authority to set the terms and conditions of parole. Some conditions are described in the regulations, including requiring reasonable assurances that the parolee

will appear at all hearings and will depart from the United States when required to do so. *See* 8 CFR 212.5(d).

Each of the DHS immigration components—USCIS, U.S. Customs and Border Protection (CBP), and U.S. Immigration and Customs Enforcement (ICE)—has been delegated the authority to parole applicants for admission in accordance with section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5). *See* 8 CFR 212.5(a). The parole authority is often utilized to permit an individual who is outside the United States to travel to and come into the United States without a visa. USCIS, however, also accepts requests for “advance parole” by individuals who seek authorization to depart the United States and return to the country pursuant to parole in the future. *See* 8 CFR 212.5(f); Application for Travel Document (Form I-131). Aliens who seek parole as entrepreneurs under this rule may need to apply for advance parole if at the time of application they are present in the United States after admission in, for example, a nonimmigrant classification, as USCIS is unable to grant parole to aliens who are not “applicants for admission.” *See* INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A); *see also* INA section 235(a)(1), 8 U.S.C. 1225(a)(1) (describing “applicants for admission”). Advance authorization of parole by USCIS does not guarantee that the individual will be paroled by CBP upon his or her appearance at a port of entry.<sup>10</sup> Rather, with a grant of advance parole, the individual is issued a document authorizing travel (in lieu of a visa) indicating “that, so long as circumstances do not meaningfully change and the DHS does not discover material information that was previously unavailable, . . . DHS’s discretion to parole him at the time of his return to a port of entry will likely be exercised favorably.”<sup>11</sup>

Currently, upon an individual’s arrival at a U.S. port of entry with a parole travel document (e.g., a Department of State (DOS) foil, Authorization for Parole of an Alien into the United States (Form I-512L), or an Employment Authorization Document (Form I-766)), a CBP officer at a port of entry inspects the prospective parolee. If parole is authorized, the CBP officer issues an Arrival/Departure Record (Form I-94) documenting the grant of parole and the length of the parolee’s

authorized parole period. *See* 8 CFR 235.1(h)(2). CBP retains the authority to deny parole to a parole applicant or to modify the length of advance parole authorized by USCIS. *See* 8 CFR 212.5(c).

Because parole does not constitute an admission, individuals may be paroled into the United States even if they are inadmissible under section 212(a) of the INA, 8 U.S.C. 1182(a). Further, parole does not provide a parolee with nonimmigrant status or lawful permanent resident status. Nor does it provide the parolee with a basis for changing status to that of a nonimmigrant or adjusting status to that of a lawful permanent resident, unless the parolee is otherwise eligible.

Under current regulations, once paroled into the United States, a parolee is eligible to request employment authorization from USCIS by filing a Form I-765 application with USCIS. *See* 8 CFR 274a.12(c)(11). If employment authorization is granted, USCIS issues the parolee an employment authorization document (EAD) with an expiration date that is commensurate with the period of parole on the parolee’s Arrival/Departure Record (Form I-94). The parolee may use this EAD to demonstrate identity and employment authorization to an employer for Form I-9 verification purposes as required by section 274A(a) and (b) of the INA, 8 U.S.C. 1324a(a) and (b). Under current regulations, the parolee is not employment authorized by virtue of being paroled, but instead only after receiving a discretionary grant of employment authorization from USCIS based on the Application for Employment Authorization.

Parole will terminate automatically upon the expiration of the authorized parole period or upon the departure of the individual from the United States. *See* 8 CFR 212.5(e)(1). Parole also may be terminated on written notice when DHS determines that the individual no longer warrants parole or through the service of a Notice to Appear (NTA). *See* 8 CFR 212.5(e)(2)(i).

#### B. Final Rule

Following careful consideration of public comments received, DHS has made several modifications to the regulatory text proposed in the NPRM (as described above in Section I.C.). The rationale for the proposed rule and the reasoning provided in the background section of that rule remain valid with respect to these regulatory amendments. Section III of this final rule includes a detailed summary and analysis of public comments that are pertinent to the proposed rule and DHS’s role in

<sup>8</sup> The denial of parole is not subject to judicial review. *See* INA section 242(a)(2)(B)(ii), 8 U.S.C. 1252(a)(2)(B)(ii); *Bolante v. Keisler*, 506 F.3d 618, 621 (7th Cir. 2007).

<sup>9</sup> The grounds for termination set forth in 212.19(k) are in addition to the general grounds for termination of parole described at 8 CFR 212.5(e).

<sup>10</sup> *See Matter of Arrabally*, 25 I. & N. Dec. at 779 n.6 (citing 71 FR 27585, 27586 n.1 (May 12, 2006)) (“[A] decision authorizing advance parole does not preclude denying parole when the alien actually arrives at a port-of-entry, should DHS determine that parole is no longer warranted.”).

<sup>11</sup> *Id.*

administering the International Entrepreneur Rule. A brief summary of comments deemed by DHS to be out of scope or unrelated to this rulemaking, making a detailed substantive response unnecessary, is provided in Section III.K. Comments may be reviewed at the Federal Docket Management System (FDMS) at <http://www.regulations.gov>, docket number USCIS-2015-0006.

### III. Public Comments on the Proposed Rule

#### A. Summary of Public Comments

In response to the proposed rule, DHS received 763 comments during the 45-day public comment period. Of these, 43 comments were duplicate submissions and approximately 242 were letters submitted through mass mailing campaigns. As those letters were sufficiently unique, DHS considered all of these comment submissions. Commenters consisted primarily of individuals but also included startup incubators, companies, venture capital firms, law firms and representatives from State and local governments. Approximately 51 percent of commenters expressed support for the rule and/or offered suggestions for improvement. Nearly 46 percent of commenters expressed general opposition to the rule without suggestions for improvement. For approximately 3 percent of the public comments, DHS could not ascertain whether the commenter supported or opposed the proposed rule.

DHS has reviewed all of the public comments received in response to the proposed rule and addresses relevant comments in this final rule. DHS's responses are grouped by subject area, with a focus on the most common issues and suggestions raised by commenters.

#### B. Legal Authority

*Comments.* One commenter supported DHS's stated authority for promulgating this regulation and said that the INA grants the Secretary of Homeland Security the authority to establish policies governing parole and that efforts to reduce barriers to entrepreneurship via regulatory reform directly addresses DHS's mandate, "to ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland." On the other hand, some commenters questioned DHS's authority to implement this rule. A commenter asserted that the rule created a new visa category which is under the exclusive purview of Congress, and therefore an illegal extension of authority by the

executive branch. Another commenter indicated that the proposed rule is too vague regarding whether "the agency intends to grant parole to aliens already present in the United States," and questioned whether the proposed exercise of parole authority is supported by legislative history, is consistent with the INA's overall statutory scheme, and whether "significant public benefit parole" as outlined in this rule is "arbitrary and capricious."

*Response.* DHS agrees with the commenter that contended that the Secretary has authority to promulgate this rule. As noted above, DHS's authority to promulgate this rule arises primarily from sections 101(b)(1)(F) and 402(4) of the HSA; sections 103(a)(1) and (3) of the INA, 8 U.S.C. 1103(a)(1), (3); section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5); and section 274A(h)(3)(B) of the INA, 8 U.S.C. 1324a(h)(3)(B). The Secretary retains broad statutory authority to exercise his discretionary parole authority based upon "significant public benefit."

DHS disagrees with the comment asserting that the proposed rule would effectively create a new visa category, which only Congress has the authority to do. *See* INA section 101(a)(15), 8 U.S.C. 1101(a)(15) (identifying nonimmigrant categories). Congress expressly empowered DHS to grant parole on a case-by-case basis, and nothing in this rule uses that authority to establish a new nonimmigrant classification. Among other things, individuals who are granted parole—which can be terminated at any time in the Secretary's discretion—are not considered to have been "admitted" to the United States, *see* INA sections 101(a)(13)(B), 212(d)(5)(A), 8 U.S.C. 1101(a)(13)(B), 1182(d)(5)(A); and cannot change to a nonimmigrant category as a parolee, *see* INA section 248(a), 8 U.S.C. 1258(a). Nor does parole confer lawful permanent resident status. To adjust status to that of a lawful permanent resident, individuals generally must, among other things, be admissible to the United States, have a family or employment-based immigrant visa immediately available to them, and not be subject to the various bars to adjustment of status. *See* INA section 245(a), (c), (k); 8 U.S.C. 1255(a), (c), (k); 8 CFR 245.1.

DHS further disagrees with the comment that this rule is inconsistent with the legislative history on parole. Under current law, Congress has expressly authorized the Secretary to grant parole on a case-by-case basis for urgent humanitarian reasons or significant public benefit. The statutory language in place today is somewhat

more restrictive than earlier versions of the parole authority, which did not always require case-by-case review and now includes additional limits on the use of parole for refugees and certain alien crewmen. *See* INA section 212(d)(5)(B), 8 U.S.C. 1182(d)(5)(B) (refugees); INA section 214(f)(2)(A), 8 U.S.C. 1184(f)(2)(A) (alien crewmen); Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104-208, div. C, sec. 602(a)-(b), 110 Stat. 3009-689 (1996) (changing the standard for parole). But the statute clearly continues to authorize the granting of parole. Across Administrations, moreover, it has been accepted that the Secretary can identify classes of individuals to consider for parole so long as each individual decision is made on a case-by-case basis according to the statutory criteria. *See, e.g.,* 8 CFR 212.5(b) (as amended in 1997); Cuban Family Reunification Parole Program, 72 FR 65,588 (Nov. 21, 2007). This rule implements the parole authority in that way.

In addition to the concerns described above, one commenter argued that the proposed rule did not clearly explain whether "the agency intends to grant parole to aliens already present in the United States." DHS believes it is clear under this rule that an individual who is present in the United States as a nonimmigrant based on an inspection and admission is not eligible for parole without first departing the United States and appearing at a U.S. port of entry to be paroled into United States. *See* INA sections 212(d)(5)(A), 235(a)(1); 8 U.S.C. 1182(d)(5)(A), 1225(a)(1). As further discussed in section III.H. of this rule, moreover, DHS does not contemplate using this rule to grant requests for parole in place for initial requests for parole.

*Comment:* A commenter objected to the extension of employment authorization by this rule to entrepreneur parolees for the sole purpose of engaging in entrepreneurial employment, stating that DHS is barred from doing so given the comprehensive legislative scheme for employment-based temporary and permanent immigration.

*Response:* DHS disagrees with the commenter. Under a plain reading of INA section 103(a), 8 U.S.C. 1103(a), the Secretary is provided with broad discretion to administer and enforce the Nation's immigration laws and broad authority to "establish such regulations . . . and perform such other acts as he deems necessary for carrying out his authority under the [INA]," *see* INA section 103(a)(3), 8 U.S.C. 1103(a)(3). Further, the specific definitional

provision at section 274A(h)(3)(B) of the INA, 8 U.S.C. 1324a(h)(3)(B), which was raised by the commenter, presumes that employment may be authorized by the Secretary and not just by statute. See *Arizona Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1062 (9th Cir. 2014) (“Congress has given the Executive Branch broad discretion to determine when noncitizens may work in the United States.”); *Perales v. Casillas*, 903 F.2d 1043, 1048, 1050 (5th Cir. 1990) (describing the authority recognized by INA 274A(h)(3) as “permissive” and largely “unfettered”). The fact that Congress has directed the Secretary to authorize employment to specific classes of foreign nationals in certain statutory provisions does not diminish the Secretary’s broad authority under other statutory provisions to administer the immigration laws, including through the extension of employment authorization. See generally 8 CFR 274a.12 (identifying, by regulation, numerous “classes of aliens authorized to accept employment”).

#### C. Significant Public Benefit

*Comment:* One commenter stated that the quality of the jobs created should be a factor in determining whether the entrepreneur’s parole will provide a significant public benefit. The commenter suggested formalizing some form of priority criteria.

*Response:* Under this final rule, evidence regarding job creation may be considered in determining whether to parole an individual into the United States for “significant public benefit.” An entrepreneur may be considered for an initial period of parole if the entrepreneur’s start-up entity has received a qualifying investment or grant. Alternatively, if the entity has received a lesser investment or grant amount, the entrepreneur may still be considered for parole by providing other reliable and compelling evidence of the start-up entity’s substantial potential for rapid growth and job creation. Evidence pertaining to the creation of jobs, as well as the characteristics of the jobs created (e.g., occupational classification and wage level) may be considered by DHS in determining whether the evidence, when combined with the amount of investment, grant or award, establishes that the entrepreneur will provide a significant public benefit to the United States. As with initial parole determinations, evidence pertaining to the creation of jobs, as well as the characteristics of the jobs created (e.g., occupational classification and wage level) may be considered by DHS to determine whether the entrepreneur should be granted re-parole.

Given the way job creation will already be considered, DHS believes it is unnecessary to make “job quality” its own separate criterion in determining whether to grant parole or re-parole. It is also unclear how the commenter believes DHS should apply any such criterion. Under this final rule, DHS will evaluate the totality of the circumstances, including the evidence about job creation, in determining whether to parole an individual into the United States for significant public benefit.

#### D. Definitions

##### 1. Entrepreneur—Ownership Criteria

*Comments:* Several commenters expressed concern with the 15 percent “substantial ownership interest” requirement in the definition of “entrepreneur” in the proposed rule. One such commenter said the 15 percent “substantial ownership interest” requirement is only reasonable for smaller startups and proposed that the rule also separately include a dollar amount to satisfy the “substantial ownership interest” requirement (e.g., 15 percent ownership interest or ownership interest valued at \$150,000 or more). Several commenters recommended that the final rule reduce the initial parole threshold from 15 to 10 percent and reduce the re-parole threshold from 10 to 5 percent. Other commenters suggested that 10 percent ownership per individual would be a more appropriate threshold because some start-ups may be founded by teams of founders that need to split equity and requiring more than 15 percent ownership might be too restrictive and limit business creativity and growth.

*Response:* Consistent with the commenters’ concerns and suggestions, DHS is revising the definition of entrepreneur in this final rule to reduce the ownership percentage that the individual must possess. See 8 CFR 212.19(a)(1). Based on further analysis, DHS believes that the thresholds from the proposed rule could have unnecessarily impacted an entrepreneur’s ability to dilute his or her ownership interest to raise additional funds and grow the start-up entity. In this final rule, an individual may be considered to possess a substantial ownership interest if he or she possesses at least a 10 percent ownership interest in the start-up entity at the time of adjudication of the initial grant of parole and possesses at least a 5 percent ownership interest in the start-up entity at the time of adjudication of a subsequent period of re-parole. DHS believes that the revised

ownership percentage requirements in this final rule adequately account for the possibility of equity dilution, while ensuring that the individual continues to have a substantial ownership interest in, and assumes more than a nominal financial risk related to, the start-up entity.

Given that this is a new and complex process, DHS declines to adopt a separate option of establishing substantial ownership interest based on a valuation of the entrepreneur’s ownership interest. DHS believes that the percentages provided within the final rule offer clear guidance to stakeholders and adjudicators as to what constitutes a substantial ownership interest regardless of the industry involved. Reliance upon valuations of an owner’s interest would unnecessarily complicate the adjudicative review process, could potentially increase fraud and abuse, and may be burdensome for the applicant to obtain from an independent and reliable source. DHS, therefore, believes that the best indicator of an entrepreneur’s ownership interest is the individual’s ownership percentage since that is easy for an applicant to establish and provides an objective indicator for DHS to assess. DHS has decided to take an incremental approach and will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

##### 2. Other Comments on Entrepreneur Definition

*Comment:* One commenter stated that, in defining who counts as an “entrepreneur,” the rule should take into account whether an individual has been successful in the past, including by having previously owned and developed businesses, generated more than a certain amount of revenue, created more than a certain number of jobs, or earned at least a certain amount.

*Response:* Under this final rule, evidence regarding an entrepreneur’s track record may be considered in determining whether to parole an individual into the United States for “significant public benefit.” The final rule’s definition of entrepreneur requires the applicant to show that he or she both: (1) Possesses a substantial ownership interest in the start-up entity, and (2) has a central and active role in the operations of that entity, such that the alien is well-positioned, due to his or her knowledge, skills, or experience, to substantially assist the entity with the growth and success of its business. See new 8 CFR 212.19(a)(1). Some of the factors suggested by the commenter are

relevant evidence that the applicant can submit to show that he or she is well-positioned to substantially assist the entity with the growth and success of its business. DHS will also evaluate the totality of the evidence to determine whether an applicant's presence in the United States will provide a significant public benefit and that he or she otherwise merits a favorable exercise of discretion. Given the way an entrepreneur's track record may already be considered on a case-by-case basis, DHS believes it is unnecessary to make the specific factors identified by the commenter their own separate criteria in determining whether to grant parole or re-parole.

*Comment:* A few commenters recommended that DHS clarify the term "well-positioned" as used in the definition of "entrepreneur." See final 8 CFR 212.19(a)(1) (requiring an international entrepreneur to prove that he or she "is well-positioned, due to his or her knowledge, skills, or experience, to substantially assist the entity with the growth and success of its business"). The commenters believe that the proposed rule did not explain how an applicant would demonstrate that he or she is "well-positioned." The commenters recommend that the "substantial ownership interest" test in the same provision should provide a rebuttable presumption that the entrepreneur is "well-positioned" and that the "significant capital financing" requirements reflect the market demand for the entrepreneur to grow the business.

*Response:* DHS believes that both the proposed rule and this final rule sufficiently explain how an applicant may establish that he or she is "well-positioned" to grow the start-up entity. An applicant may generally establish that he or she is well-positioned to advance the entity's business by providing evidence that he or she: (1) Possesses a significant (at least 10 percent) ownership interest in the entity at the time of adjudication of the initial grant of parole, and (2) has an active and central role in the operations and future growth of the entity, such that his or her knowledge, skills, or experience would substantially assist the entity in conducting and growing its business in the United States. Such an applicant cannot be a mere investor. The applicant must be central to the entity's business and well-positioned to actively assist in the growth of that business, such that his or her presence would help the entity create jobs, spur research and development, or provide other benefits to the United States. Whether an applicant has an "active and central

role," and therefore is well-positioned to advance the entity's business, will be determined based on the totality of the evidence provided on a case-by-case basis. Such evidence may include:

- Letters from relevant government agencies, qualified investors, or established business associations with an understanding of the applicant's knowledge, skills or experience that would advance the entity's business;
- news articles or other similar evidence indicating that the applicant has received significant attention and recognition;
- documentation showing that the applicant or entity has been recently invited to participate in, is currently participating in, or has graduated from one or more established and reputable start-up accelerators;
- documentation showing that the applicant has played an active and central role in the success of prior start-up or other relevant business entities;
- degrees or other documentation indicating that the applicant has knowledge, skills, or experience that would significantly advance the entity's business;
- documentation pertaining to intellectual property of the start-up entity, such as a patent, that was obtained by the applicant or as a result of the applicant's efforts and expertise;
- a position description of the applicant's role in the operations of the company; and
- any other relevant, probative, and credible evidence indicating the applicant's ability to advance the entity's business in the United States.

Particularly given the way this evidence will be evaluated on a case-by-case basis, and the need to ensure parole is justified by significant public benefit, DHS declines to adopt the commenters' suggestion of adopting a rebuttable presumption that certain applicants meet the "well-positioned" requirement. The burden of proof remains with the applicant.

*Comment:* One commenter representing a group of technology companies recommended that DHS add the term "intellectual property" as a metric that an adjudicator would take into consideration when determining the "active and central role" that the international entrepreneur performs in the organization. The commenter noted that it had several member companies that have non-citizen inventors on a key patent application, and have had core intellectual property developed by non-citizens, often within the university environment. In many of these situations, the non-citizen inventors were unable to obtain work

authorization and join the emerging startup company, resulting in loss of key technical ability, delay, and additional cost for the startup company to achieve market success. The commenter believes this rule could alleviate this investment risk.

*Response:* As discussed above, an applicant for parole under this rule may provide any relevant, probative, and credible evidence indicating the applicant's ability to advance the entity's business in the United States. Such evidence includes documentation pertaining to intellectual property of the start-up entity, such as a patent, that was obtained by the applicant or as a result of the applicant's efforts and expertise. DHS will consider such evidence to determine whether the applicant performs, or will perform, an active and central role in the start-up entity.

Given the breadth of evidence that can already be considered in these determinations, DHS declines to amend the definition of "entrepreneur" in 8 CFR 212.19(a)(1) to include some consideration of "intellectual property" as a specific metric to determine if the applicant will have an active and central role in the start-up entity. DHS believes it is appropriate to allow for sufficient flexibility in the definition for adjudicators to evaluate each case on its own merits. Given the considerable range of entrepreneurial ventures that might form the basis for an application for parole under this rule, DHS believes that such flexibility is important to ensure that cutting edge industries or groundbreaking ventures are not precluded from consideration simply because of an overly rigid or narrow definition of "entrepreneur."

*Comment:* One commenter noted that DHS's inclusion of criteria in section IV.B.1. of the NPRM, "Recent Formation of a Start-Up Entity," is reminiscent of criteria used in the O-1 nonimmigrant classification for individuals with extraordinary ability, except for the focus on entrepreneurial endeavors. The commenter especially welcomed the final "catch-all" that referenced "any other relevant, probative, and credible evidence indicating the entity's potential for growth." The commenter asserted that as it pertains to "newspaper articles," one of the major difficulties of the O-1 petition process is the lack of awareness by adjudicators of tech-press publications, such as Recode or TechCrunch. The commenter explained that coverage in these publications is very valuable to startups, and forcing startups to garner traditional media coverage in publications like the *Wall Street Journal* or the *New York*

*Times* is often counterproductive towards the entrepreneur's success.

*Response:* DHS agrees with the commenter that the list of evidence provided in the preamble to the NPRM and this final rule provides an illustrative, non-exhaustive list of the types of evidence that might be submitted by an applicant to establish that he or she meets the definition of entrepreneur in 8 CFR 212.19(a)(1). Applicants may submit any relevant, probative and credible evidence that demonstrates the entity's potential for growth, including tech-press publications.

*Comment:* One commenter recommended broadening the proposed requirement that the parolee play a central role in operations. The commenter noted that the DHS November 2014 memorandum,<sup>12</sup> which initially directed USCIS to develop a proposed rule under the Secretary's parole authority, refers to researchers, not just managers or founders. The commenter stated that in the technology world, "technical founders" are key employees who lead the research and development phase, and recommended that these technical founders be included even if they are not managing overall operations. To keep this expansion targeted, the commenter recommended requiring a technical founder to have an advanced degree in a STEM field from a U.S. institution of higher education.

*Response:* DHS agrees that "technical founders" are often key employees who play an important role in the development and success of a start-up entity. DHS disagrees, however, with the commenter's assertion that the definition of entrepreneur in 8 CFR 212.19(a)(1) does not sufficiently encompass technical founders. Technical founders can perform a central and active role in the operations of their start-up entity, and may be well-positioned, due to their knowledge, skills, or experience, to substantially assist the entity with the growth and success of its business. The definition of "entrepreneur" is not limited to those individuals who manage the overall operations of the start-up entity. Thus, DHS believes it is unnecessary to broaden the definition of "entrepreneur" in the way the commenter suggests.

*Comment:* One commenter suggested that the rule should provide a clear-cut definition of a typical entrepreneur.

This commenter asserted that the draft rule does not adequately account for situations where a typical entrepreneur partially qualifies or does not qualify for parole, but nevertheless seeks to start a business in the United States. The commenter stated that USCIS and the White House should plan to have a separate case study team to evaluate each application.

*Response:* DHS believes that the rule provides a reasonable and clear definition of an entrepreneur. This rule is not designed or intended to provide parole to everyone who seeks to be an entrepreneur, but will instead provide a framework for case-by-case determinations based upon specified criteria for determining that a grant of parole in this context provides a significant public benefit. The framework in this rule is consistent with DHS's parole authority under INA section 212(a)(5), 8 U.S.C. 1182(a)(5), and is based on the statutory authorization to provide parole for significant public benefit. Each application for parole under this rule will be adjudicated by an Immigration Services Officer trained on the requirements for significant public benefit parole under 8 CFR 212.19. DHS believes that a separate case-study team could unnecessarily complicate and delay adjudications and declines to adopt the commenter's suggestion.

### 3. Definition of Start-Up Entity— "Recently-Formed" and the 3-year Limitation

*Comment:* Several commenters expressed concern with the definition of "start-up entity" and the requirement that an entity, in order to satisfy that definition, must have been created within the 3 years immediately preceding the parole request filing date. A few individual commenters said that the 3-year limitation could be inadequate in certain situations, such as when investing in an inactive business with other co-founders to initiate the start-up, or when investing in high-priority areas like healthcare, biotechnology, and clean energy that have long gestation times. A couple of individual commenters said that the 3-year limitation may not be necessary given the other, more stringent requirements in the proposed rule. Some commenters provided the following recommendations relating to the 3-year limitation: Eliminate the limitation, lengthen the period to 5 years, lengthen the period to 10 years, or include a case-by-case provision allowing for submissions that may satisfy the definition of "start-up entity." One commenter recommended

that "recently formed" should include entities formed within the last 10 years, and also requested that where applicable, DHS accept alternative evidence to determine and establish that the company is a "start-up" entity, such as letters of attestation from investors, industry experts within a particular niche field, and government agencies that speak to the average growth cycle of a new company within a particular area. A few commenters stated that the 3-year limitation was appropriate.

*Response:* In response to these comments, DHS revised proposed 8 CFR 212.19(a)(2) and the definition of "start-up entity" in this final rule to require that the entity must have been formed within the 5 years immediately preceding the filing of the initial parole application, rather than 3 years as proposed. DHS believes that this definition appropriately reflects that some entities, particularly given the industry in which the entity operates, may require a longer gestation time before receiving substantial investment, grants, or awards. This 5-year limitation continues to reflect the Department's intention for parole under this final rule: To incentivize and support the creation and growth of new businesses in the United States, so that the country may benefit from their substantial potential for rapid growth and job creation. DHS recognizes that the term "start-up" is usually used to refer to entities in early stages of development, including various financing rounds used to raise capital and expand the new business, but the term "goes beyond a company just getting off the ground."<sup>13</sup> Limiting the definition of "start-up" in this proposed rule to entities that are less than 5 years old at the time the parole application is filed is a reasonable way to help ensure that the entrepreneur's entity is the type of new business likely to experience rapid growth and job creation, while still allowing a reasonable amount of time for the entrepreneur to form the business and obtain qualifying levels of investor financing (which may occur in several rounds) or government grants or awards.

### 4. Other Comments on the Definition of Start-up Entity

*Comment:* One commenter said that formation should be defined to be either the creation of a legal entity under which the activities of the business

<sup>12</sup> Memorandum from Jeh Johnson, DHS Secretary, Policies Supporting U.S. High-Skilled Business and Workers 4 (Nov. 20, 2014), at [https://www.dhs.gov/sites/default/files/publications/14\\_1120\\_memo\\_business\\_actions.pdf](https://www.dhs.gov/sites/default/files/publications/14_1120_memo_business_actions.pdf).

<sup>13</sup> U.S. Small Business Administration, Startups & High Growth Businesses, available at <https://www.sba.gov/content/startups-high-growth-businesses> ("In the world of business, the word 'startup' goes beyond a company just getting off the ground.").



would be conducted or the effective date of an agreement between the entrepreneur and an existing business to launch the business activities as a start-up, branch, department, subsidiary, or other activity of an existing business entity. Another commenter suggested that DHS consider restructuring (e.g., use successor-in-interest rules) and other pivots (in terms of changes in the service or product, as well as markets) during the 3-year period immediately preceding the filing of the parole application and at time of application for re-parole.

*Response:* DHS appreciates the commenters' suggestions and notes that recent formation within the definition of "start-up entity" in 8 CFR 212.19(a)(2) is already limited to the creation of the entity within the 5 years immediately preceding the filing date of the alien's initial parole request. DHS further declines to amend 8 CFR 212.19(a)(2) to broaden what may be considered "recently formed" to include the effective date of an agreement between the entrepreneur and an existing business to launch new business activities, restructurings and other pivots. Given that this is a new and complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

*Comment:* One commenter suggested that start-up entities under this rule should be limited to businesses that fill a need that is currently not being fulfilled in the United States.

*Response:* One of the goals of this final rule is to increase and enhance entrepreneurship, innovation, and job creation in the United States; and, under this rule, evidence regarding the expected contributions of a start-up entity will be considered in determining whether to parole an individual into the United States. A successful start-up entity, particularly one with high-growth potential, will fulfill an identified business need. For example, the entrepreneur may be starting the business to alter an existing industry through innovative products or processes, innovative and more efficient methods of production, or cutting-edge research and development to expand an existing market or industry. It is also unclear from the commenter's suggestion how "business need" would be defined, and DHS believes that attempting to do so in this rule could result in an overly restrictive definition that fails to account for future innovation, would be unnecessarily rigid, and would lessen the rule's ability

to retain and attract international entrepreneurs who will provide a significant public benefit to the United States.

*Comment:* An individual commenter requested that staffing companies be included as a type of startup.

*Response:* In this final rule, and for purposes of parole under this program, DHS defines a "start-up entity" as a U.S. business entity that was recently formed, has lawfully done business during any period of operation since its date of formation, and has substantial potential for rapid growth and job creation. See 8 CFR 212.19(a)(2). The rule requires that entities meet certain specified criteria for obtaining parole, but the rule does not specifically exclude staffing companies from participating if they otherwise meet these criteria. DHS therefore will not revise the definition of start-up entity in this rule as requested by the commenter.

*Comment:* One commenter asserted that the rule fails to specify how a start-up entity can demonstrate that it has "lawfully done business" or "has substantial potential for rapid growth and job creation." The commenter recommended revising the definition to more closely align with 8 CFR 214.2(l)(1)(ii)(G)(2) and (l)(1)(ii)(H) by instead requiring evidence that the entity is or will be engaged in the regular, systematic, and continuous provision of goods or services. This commenter suggested that the submission of expert witness testimony by a reputable third party, such as a recognized professor or leader in the start-up entity's proposed field, should be given deference and treated under the final rule as a rebuttable presumption establishing that the start-up "has substantial potential for rapid growth and job creation."

*Response:* DHS declines to adopt the commenter's suggested changes in this final rule. DHS believes that an applicant can demonstrate the start-up entity's lawful business activities through many different means and will keep this requirement flexible to account for the many differences among start-up entities. Such evidence might include, but is not limited to, business permits, equipment purchased or rented, contracts for products or services, invoices, licensing agreements, federal tax returns, sales tax filings, and evidence of marketing efforts.

DHS believes that the rule provides a clear framework for establishing that a start-up entity has substantial potential for rapid growth and job creation. See 8 CFR 212.19(b)(2)(ii) and (iii). An applicant generally must satisfy the criteria in 8 CFR 212.19(b)(2)(ii) to be

considered for parole under this rule. An applicant who only partially meets one or both of the criteria in 8 CFR 212.19(b)(2)(ii) may still be eligible for consideration for parole under this rule if the applicant provides additional reliable and compelling evidence that the start-up entity has the substantial potential for rapid growth and job creation. DHS recognizes that the rule does not provide specific evidence that must be submitted in order to satisfy the alternative criteria in 8 CFR 212.19(b)(2)(iii). DHS believes that providing a specific set of evidence would have the unintended effect of narrowing a provision that was designed to allow for the submission of any evidence that the applicant believes may establish the substantial potential of his or her start-up entity, recognizing that such evidence may vary depending on the nature of the business and the industry in which it operates. DHS believes that it is important to retain criteria that provide flexibility to the applicant and DHS. Such flexibility is consistent with DHS's parole authority and the case-by-case nature of each parole determination as required by statute. See INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).

DHS does not believe that the rule should be revised to align with 8 CFR 214.2(l)(1)(ii)(G)(2) and (l)(1)(ii)(H). The requirements set forth in 8 CFR 214.2(l)(1)(ii)(G)(2) and (l)(1)(ii)(H) relate specifically to eligibility for classification as an L-1 nonimmigrant and are not necessarily relevant to the requirements set forth in this rule, which are specifically designed to provide the framework by which USCIS will determine whether to grant parole to certain individuals for significant public benefit. Particularly given the way this evidence will be evaluated on a case-by-case basis, and the need to ensure parole is justified by significant public benefit, DHS declines to adopt the commenters' suggestion of adopting a rebuttable presumption that certain entities have substantial potential for rapid growth and job creation. The burden of proof remains with the applicant.

##### 5. Qualified Government Award or Grant

*Comment:* One commenter stated that the rule's grant-based criteria for consideration focused too narrowly on awards made by government entities. The commenter noted that entrepreneurs seek grants from a variety of sources and that funding from non-profits or not-for-profit entities (such as U.S. universities) can be significant sources of start-up capital. The

commenter requested that the rule be revised to allow entrepreneurs of non-profit start-up entities to qualify for parole under this program based on the receipt of charitable grants.

*Response:* DHS appreciates the commenter's suggestion, but declines to adopt the suggestion in this final rule to include charitable grants as a type of qualifying grant or award under 8 CFR 212.19(a)(3). DHS believes, given the nature of charitable grants, that they would not present the same level of validation regarding the entity's high-growth potential as would a grant or award from a Federal, State, or local government entity with expertise in economic development, research and development, or job creation. Since the validating quality of a substantial government grant or award is an important factor DHS will rely upon to determine if the entrepreneur will provide a significant public benefit to the United States, and since that same validating quality does not necessarily extend to charitable grants or awards, DHS declines to adopt the commenter's suggestion. DHS notes, however, that nothing in this final rule prohibits entrepreneurs from accepting charitable grants or pointing to such funding as evidence that parole would be justified and that they merit a favorable exercise of discretion. Moreover, given that this is a new and complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

*Comment:* One commenter noted that the definition of qualified government award or grant and the phrase "federal, state, or local government entity," are ambiguous as to whether an entrepreneur may qualify under the rule based on a grant by a foreign government. According to the commenter, the rule does not explicitly state that the "federal, state, or local government entity" needs to be restricted to entities in the United States. The commenter encouraged USCIS to adopt a broad approach in determining which kinds of grants may qualify and to allow entrepreneurs to qualify if their start-up entity attracts substantial foreign government financing. The commenter also suggested that USCIS and CBP should again emphasize that parole may be discretionarily denied in cases that could risk national security or impair international relations.

*Response:* While DHS always maintains the ability to deny parole in its discretion, including in those cases where there may be a national security

or foreign relations concerns, DHS declines to expand the definition of qualified government grant or award to include grants or awards from a foreign governmental entity. To eliminate potential confusion, DHS is revising the definition as proposed to specifically exclude foreign government entities. The receipt of significant funding from certain U.S. federal, state or local government entities is an important factor that DHS will weigh in determining if the entrepreneur will provide a significant public benefit to the United States. DHS believes that significant funding from certain U.S. federal, state or local governmental entities is a strong indicator of a start-up entity's substantial potential for rapid growth, including through enhancing innovation, generating revenue, obtaining significant additional investments of capital, and creating jobs. Such government entities regularly evaluate the potential of U.S. businesses, so the choice to provide a significant award or grant to a particular start-up entity can be a compelling indicator of that start-up's substantial potential for rapid growth and job creation. Because these government entities are formed to serve the U.S. public, their choice to fund a particular business may be more indicative than that of a foreign government as to whether the business's operations would provide a significant public benefit in the United States. DHS believes that the reliability and weight of the independent assessment performed by certain U.S. federal, state or local governmental entities before issuing a grant or award does not necessarily extend to grants or awards made by foreign governmental entities. DHS therefore declines to adopt the commenter's suggestion to revise the rule to include funding from foreign governmental entities as one of the criteria in 8 CFR 212.19(a)(3).

#### 6. Qualified Investment

*Comment:* Some commenters suggested that DHS define "capital" broadly to include cash, cash equivalents, secured or unsecured loan proceeds, payments for or obligations under binding leases, the value of goods, equipment, and intangible property such as patent rights, trademarks, trade secrets, and distinctive "know how."

*Response:* DHS declines to adopt the commenters' suggestions. "Qualified investment" as a general criterion for parole is limited to a specific monetary investment in the form of equity or convertible debt, to ensure that the investment is easily valued as well as

significant in nature. This promotes fair and efficient administration of the process under this rule, while also ensuring the integrity of that process. In addition, equity investments and convertible debt investments both involve a distinctive level of expert review, due diligence, and oversight. For example, according to the Small Business Administration, venture capital firms and angel investors typically review a business plan and evaluate a start-up's management team, market, products and services, operating history, corporate governance documents, and financial statements before making an equity investment.<sup>14</sup> Such investment generally also involves active monitoring via board participation, strategic marketing, governance, and capital structure.<sup>15</sup> While non-monetary contributions made to a start-up entity may not be considered as a qualified investment for purposes of the general criteria of a parole determination under this rule, the rule does not prohibit such contributions and they may be considered as evidence under the alternative criteria at 8 CFR 212.19(b)(2)(iii) and (c)(2)(iii) to establish that the start-up entity has, or continues to have, substantial potential for rapid growth and job creation.

*Comment:* One commenter stated that the requirement that start-up capital must be equity or convertible debt may be too limiting given the venture finance markets today. The commenter said that other investment instruments are commonly used by sophisticated market participants, and that such investments might not technically be considered equity or convertible debt even though they are bona fide capital investments. The commenter recommended that the definition be made "future-proof" by creating a catch-all for other investment instruments that are convertible, exchangeable, or exercisable for equity in the start-up, regardless of the name of the investment instrument.

*Response:* DHS understands that the regulatory text may not capture all possible future investment instruments and has amended the regulatory text to capture other commonly used convertible securities now and in the future. The final rule defines "qualified investment" as an investment made in good faith, and that is not an attempt to circumvent any limitations imposed on investments under this section, of lawfully derived capital in a start-up

<sup>14</sup> Venture Capital, <https://www.sba.gov/starting-business/finance-your-business/venture-capital/venture-capital>.

<sup>15</sup> *Id.*

entity that is a purchase from such entity of its equity, convertible debt or other security convertible into its equity commonly used in financing transactions within such entity's industry. DHS believes that this definition, in practice, will apply to other securities convertible into equity (other than convertible debt) that are or become commonly used within the start-up entity's industry, and DHS may issue additional guidance in the future regarding such securities as necessary. Given that this program is new and complex, DHS has decided to take an incremental approach and will consider potential modifications in the future after it is able to assess implementation of the rule and its impact on operational resources.

### 7. Qualified Investor

*Comment:* Several commenters, including associations and individual commenters, stated that the proposed "qualified investor" definition is more stringent than the "accredited investor" definition adopted by the Securities and Exchange Commission (SEC). Several commenters stated that many angel investors, especially newer investment firms and angels, would not be considered "qualified investors" under this rule. One of these commenters suggested revising the definition of a qualified investor using the guidelines set forth by AngelList, which requires all syndicate leads on their site to have registered as accredited investors, to have made at least two direct investments in technology start-ups, and to have attracted additional funding beyond the syndicate lead. Some commenters generally stated that many potentially high-growth firms started by international entrepreneurs will not qualify for parole or re-parole because the business did not receive an investment from a qualified U.S. investor, and encouraged the rule to be more flexible to allow for additional sources of capital.

*Response:* In response to comments received, DHS is revising proposed 8 CFR 212.19(a)(5), which provides the definition of a qualified investor. For purposes of this section, such an individual or organization may be considered a qualified investor if, during the preceding 5 years, the individual or organization made investments in start-up entities in exchange for equity or convertible debt or other security convertible into equity commonly used in financing transactions within their respective industries comprising a total in such 5-year period of no less than \$600,000. See final 8 CFR 212.19(a)(5)(i). DHS has

removed the proposed requirement that the total investment amount be made in 3 separate calendar years and, consistent with its analysis of relevant investment data, reduced the amount from \$1,000,000 to \$600,000.<sup>16</sup> DHS is also making revisions consistent with the change to the qualified investment definition by adding "other securities that are convertible into equity issued by such an entity and that are commonly used in financing transactions within such entity's industry." DHS agrees with commenters that the qualified investor requirement is more stringent than the SEC "accredited investor" definition, but believes the additional parameters for qualified investors under the rule are appropriate. The "accredited investor" definition for SEC purposes is focused on the investing entity's assets or the individual investor's net worth or annual income,<sup>17</sup> not on the investor's

<sup>16</sup> To arrive at this level, DHS relied on the \$250,000 median seed round for active firms that successfully exited accelerators, as is described more fully in the "Volume Projections" subsection of the "Statutory and Regulatory Requirements" section of this final rule notice. Second, DHS multiplied this figure by 2.4, which is an estimate of the average number of investments made over a five-year period by qualified investors. DHS arrived at the figure for average investments over five years using the following methodology. DHS used the "investor graph" section of the Seed DB data set to extract investment round information for investors that have invested in various startup accelerators' portfolio companies. The search engine is not set up in a manner in which random sampling can be done, so DHS obtained data for nine accelerators chosen from the 2016 Seed Accelerator Rankings project (SARP), the report of which is found at: [http://seedrankings.com/pdf/sarp\\_2016\\_accelerator\\_rankings.pdf](http://seedrankings.com/pdf/sarp_2016_accelerator_rankings.pdf). SARP ranks accelerators via a composite scoring system based on various metrics, including funding value averages and exit performance, and produces a list of the top-rated accelerators, although there is no pre-set number of accelerators that can appear in the ranking list each year. In the 2016 SARP report there were twenty-three Seed Accelerators ranked out of a total of 160 that the program tracks. DHS was able to extract investment round data from nine of the twenty-three SARP ranked accelerators, for a total of about 3,600 individual investment rounds. Next, DHS grouped these rounds for the five-year period October 2011–November 2016 to result in 3,085 records. Next, DHS removed duplicates to parse the list into records for unique investor names. As a result, 1,329 unique investors remained. Dividing the 3,085 by 1,329 investors yields an average of 2.4, which DHS used as a reasonable estimate of the average number of investments that qualified investors made in a five year period, at least for the specific accelerators involved. DHS notes that there are several caveats to this analysis. First, the data only includes investments made through accelerators. If non-accelerator investments were included, for which DHS could not obtain data, the average would likely be higher. Second, some rounds did not include an amount and some investor names appeared with variations. DHS conducted several data runs based on different filtering techniques and generally the range of average investments was between 2.32 and 2.5.

<sup>17</sup> 17 CFR 230.501(a).

track record of successfully investing in start-up entities. An investor's successful track record of investing in start-up entities provides an important measure of objective validation that DHS will rely upon as part of evaluating whether granting parole to a particular individual would provide a significant public benefit.

DHS also declines to adopt the investor track record criteria associated with AngelList's requirements, as DHS believes that the past success of qualified investors can be demonstrated sufficiently by utilizing the criteria set forth in the final rule. DHS has maintained the requirements under 8 CFR 212.19(a)(5)(ii) as evidence that the investor has had previous successful investments, which are similar to certain criteria for a start-up entity to demonstrate eligibility for re-parole under this rule. See final 8 CFR 212.19(a)(5)(ii).

*Comment:* A joint submission from an advocacy group and a non-profit organization proposed that DHS create a "whitelist" of qualified investors and modify the rule such that any start-up receiving an investment from a whitelisted investor proceed through an expedited review process. The commenter said that this would both streamline the parole process and diminish the burden on adjudicators to analyze the merits of often complicated technology companies. The commenter said that the qualification process for such an investor whitelist could be significantly more robust than the rule's proposed definition of "qualified investor" and should be updated on an annual or biannual basis. Another joint submission suggested the creation of a "Known Qualified Investor" program, similar to the "Known Employer" pilot program recently created by DHS in a different context, to assist the overall adjudication process.

*Response:* DHS appreciates the commenters' suggestions. The Known Employer program referenced by the commenter remains in a pilot stage. DHS will assess the effectiveness of the Known Employer program after the pilot is complete, and then determine whether the program should be made permanent. If the program is successful, DHS will assess whether it may be expanded to other adjudication contexts. Committing to use a similar program in the context of this rulemaking would thus be premature. DHS also declines to adopt the commenters' suggestion to create a "whitelist of qualified investors" and an expedited process for applications based on investment from such investors at this time. Given that this is a new and

complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after the Department has assessed the implementation the process and its impact on operational resources.

#### 8. Evidence Required To Establish Qualified Investor

*Comment:* Several commenters expressed concern about the burden of proving that investors have met the revenue and job creation criteria in the definition of qualified investor, which the commenters said could prevent investors from participating. One commenter stated that early-stage investors usually do not keep records of employees or the revenues of their portfolio companies, and that those companies would not be inclined to respond to paperwork requests from their investors that do not relate to their own success. Another commenter said that some investors do not make their investments known publicly and the vast majority of investors do not make public their returns (let alone the number of jobs created). Another commenter said that the rule should only require evidence of publicly available information, concluding that it would be too invasive to require disclosure of confidential employee data or other confidential financial information of third-party companies that have no ties to the start-up entity related to the parole applicant. A few commenters requested that DHS allow venture capitalists, accelerators, and incubators to register so that they would not be required to produce the evidence of their qualifications with each parole application.

*Response:* DHS does not believe that providing evidence of revenues generated or jobs created by entities in which the investor previously invested is overly burdensome or would require the investor to publicly reveal otherwise sensitive information. DHS believes, given the significance of an investor's track record of successful investment in start-ups to the determination of significant public benefit, that the need for this evidence outweighs the potential burden on the applicant and investor to compile and submit it. However, as DHS continues to assess the implementation of the process once the rule is final, the Department will consider potential ways to modify the process given the kinds of issues raised by these comments.

#### 9. Foreign Funding/Investment

*Comment:* Several commenters provided input on the proposed requirement that "qualified investor"

funds must come from either U.S. citizens, lawful permanent residents, or entities that are majority owned and controlled by U.S. citizens or lawful permanent residents. Nearly all commenters on this topic expressed concerns about this requirement as a major limiting factor of the rule. Some commenters focused on the potential economic benefits of broadening the definition of "qualified investor" to include foreign investment. These commenters asserted that it would be economically beneficial to allow non-U.S. investments, as there are many experienced investors from outside the United States that could bring direct foreign investment into the country and create jobs. Another commenter stated that, by limiting qualification to domestic investors, DHS is foregoing a critical opportunity to attract foreign entrepreneurs and their investments.

*Response:* DHS disagrees with the assertion that this rule precludes or otherwise discourages foreign investment. This rule does not preclude entrepreneurs from seeking and obtaining investment from any number of sources, whether that is foreign investment, personal funds, or funds from friends and family. This rule, however, does limit the types of investment that will be considered by DHS as a qualifying investment for purpose of determining if the entrepreneur and his or her start-up entity meet the requirements for consideration for parole set out in 8 CFR 212.19. DHS believes it is important to limit the type and source of investment that will be considered a qualifying investment, since the investment is meant to serve in part as an objective way to help ensure and validate that the start-up entity's activities will benefit the United States. DHS does not believe investments from foreign sources—which are significantly more difficult for DHS to evaluate for legitimacy and screen for indicators of fraud and abuse—would provide the same measure of objective validation.

*Comment:* Multiple commenters stated that eligibility criteria should focus exclusively on the location of the start-up entity and its related growth and job creation, not on the citizenship and residence of the investor. Some commenters stated that excluding foreign investors from the definition of "qualified investors" is unduly limiting, because many high-potential international entrepreneurs might not have a pre-existing relationship with a U.S.-based investor. Commenters state that such entrepreneurs, especially if living in other countries, would have difficulty attracting investment from

U.S. investors and becoming eligible for parole under this rule. Another commenter cited data concluding that foreign entrepreneurs currently outside of the United States are at a particular disadvantage, as they lack access to U.S.-based angel and venture funding.

*Response:* DHS agrees that the U.S. location of the start-up entity and its related growth and job creation should be a critical component of eligibility under this rule in order to help ensure the exercise of parole is justified by significant public benefit to the United States. DHS believes, however, that the "qualifying investor" must also be a U.S. citizen or lawful permanent resident or an entity that is majority owned or controlled by U.S. citizens or lawful permanent residents. DHS can evaluate more rapidly, precisely, and effectively whether these investors have an established track record of prior investments, in part due to greater access to relevant and reliable records. Such investors will also be subject to the laws of the United States, which provides some additional assurance that the entrepreneurs they back will provide a significant public benefit to the United States.

DHS is not prohibiting foreign investors from investing in the entrepreneur's start-up entity, but rather is simply limiting those investors that can serve as "qualified investors" for purposes of establishing the entrepreneur's eligibility for parole under this rule. DHS anticipates that entrepreneurs living outside the United States will be able to demonstrate eligibility for parole consideration under this rule, whether based on investment from U.S. investors, grants or awards from certain U.S. Government entities, or a mixture of alternative criteria. For all the reasons above, the definition of "qualified investor" will help DHS manage an efficient process for adjudicating requests under this rule while appropriately screening for potential fraud or abuse and ensuring that each grant of parole is justified by significant public benefit to the United States.

*Comment:* Other commenters focused on specific ways that DHS might allow applicants to use foreign investment to establish their eligibility for parole consideration, including by limiting such investment to the entrepreneur's country of origin, or to only those foreign investors who do not present a national security concern. A few commenters asserted that DHS has the capability to verify the bona fides of foreign investors through, for example, the following mechanisms: Making inquiries through U.S. embassy officials,

requesting resumes and the investment history for foreign angel investors, requesting similar documentation used by EB-5 petitioners to establish their lawful source of funds, and consulting publicly available data on reputable foreign investors with a history of successful investments in various countries. Some commenters provided suggestions for alternative or revised definitions relating to foreign investors that could remain easily verifiable by DHS, with the burden being on the investor, including (1) professionally managed funds with at least \$10 million under management and registered with the local jurisdiction, and (2) angel investors that have made credible investments in U.S. companies under the same standards as U.S. “qualified investors.” Finally, an individual commenter expressed concerns that even investments from U.S. sources could be suspect, and could serve as a pass-through for ineligible investors such as the entrepreneur’s family or foreign nationals.

*Response:* While DHS understands that international entrepreneurs can attract legitimate investment capital from non-U.S. sources, DHS believes—as explained at greater length above—that it is appropriate and important to require that a “qualified investment” come from a U.S. source as one of the general criteria to establish that the start-up entity has the substantial potential for rapid growth and job creation. DHS is prepared to monitor the bona fide nature of such U.S.-based investments, as described in greater detail above. Moreover, the rule neither precludes an applicant from securing funding from non-U.S. sources nor precludes such funding from being considered, non-exclusively, under the alternative criteria at 8 CFR 212.19(b)(2)(iii) or (c)(2)(iii). Given that this is a new and complex process, DHS will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

#### 10. Self-Funding/“Bootstrapping”

*Comment:* Several commenters argued that entrepreneurs should be able to demonstrate eligibility for parole under this rule not only through funding from U.S. investors or U.S. Government entities, but also through self-financing (known as “bootstrapping”). One commenter noted that many highly successful start-up founders initially grew their companies through bootstrapping, not by raising capital from external investors.

*Response:* DHS declines to expand the definition of “qualified investment” to

include self-funding by the entrepreneur applicant. DHS believes that this definition should include only those investors who have a history of making similar investments over a 5-year period and who can demonstrate that at least two of the entities receiving such investments have subsequently experienced significant growth in revenue or job creation. See final 8 CFR 212.19(a)(5). DHS believes that the investment of a substantial amount of capital by qualified investors in an entrepreneur’s start-up entity can serve as a strong indication of the entity’s substantial and demonstrated potential for rapid business growth and job creation. Self-funding, while a rational financing strategy for many entrepreneurs, does not provide the same objective and external validation that DHS requires in assessing whether granting parole to an individual is justified based on significant public benefit.

#### 11. Other Comments on Qualified Investors

##### a. Crowdfunding

*Comment:* Several commenters stated that the rule should allow crowdfunding as a qualified investment. These commenters noted that entrepreneurs have raised over a billion dollars in investments through various types of crowdfunding platforms, which serve to broaden the base of available investors and demonstrate a venture’s potential growth. Commenters also cited the Jumpstart Our Business Startups Act (JOBS Act) of 2012, which created a national regulatory framework for securities-based crowdfunding platforms in particular, along with public statements suggesting that securities-based crowdfunding is recognized by Congress and the Administration as a valuable and increasingly-used investment tool. One commenter also stated that allowing the use of crowdfunding platforms would increase the pool of potential applicants for entrepreneurial parole and could provide a workable intermediary for foreign investment in eligible start-up entities. One commenter suggested potential requirements that would facilitate the use of crowdfunding investment sources, such as setting a threshold amount for eligible crowdfunding investments and confirming that such investments have been deposited in the start-up entity’s bank account after the end of the crowdfunding campaign.

*Response:* DHS appreciates the commenters’ suggestions. Investments made in a start-up entity through an

SEC-compliant intermediary, such as an SEC-compliant crowdfunding platform, will be treated no differently for purposes of this rule than had the investments been made directly. In order to promote the integrity of adjudications under this rule, DHS declines to make changes to the definition of “qualified investor” that would effectively treat funds generated through crowdfunding platforms as a different class of eligible investment. DHS notes, however, that evidence of a successful donation-based or securities-based crowdfunding campaign could be provided under the rule’s alternative eligibility criteria.

##### b. Established U.S. Investors

*Comment:* One commenter questioned the requirement that capital be received “from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities.” The commenter stated that the requirement increases the relative bargaining power of established investors working with entrepreneurs seeking parole under this rule, while diminishing that of new venture capital firms, new angel investors, and new start-up accelerators. The commenter stated that if it is kept in its current form, the rule is not clear whether an investment from a non-established investor would jeopardize the parole eligibility of an entrepreneur whose start-up entity is also funded by established investors.

*Response:* The definition of “qualified investor, including the requirement that an investor have a history of substantial investment in successful start-up entities, is intended to help ensure that such investors are bona fide and not concealing fraud or other illicit activity—and thus protect the integrity of the parole process under this rule. The definition is also intended to ensure that a qualifying investment serves as a strong and reliable indicator of the start-up entity’s substantial potential for rapid growth and job creation, which is relevant to assessing whether granting parole to an entrepreneur is justified by significant public benefit.

DHS emphasizes that the rule does not prohibit investment from U.S. investors who do not have an established track record of substantial investment in start-up entities under the rule’s definition of “qualified investor.” Any investment from an investor who is not a qualified investor, however, will not count toward the minimum investment criteria associated with the initial parole period or re-parole period. DHS will, of course, monitor all

elements of an application for evidence of fraud or other illegal or illicit activities. It will also assess the totality of the evidence in evaluating whether granting parole to an entrepreneur is justified by significant public benefit.

### c. Approved Regional Centers

*Comment:* One commenter requested that USCIS-approved Regional Centers (based on an approved Form I-924) be allowed to qualify as established U.S. investors. The commenter stated that investment by a Regional Center in a U.S. start-up entity would be a natural extension of what Regional Centers already do, since Regional Centers pool investment for qualified EB-5 visa projects.

*Response:* DHS believes it is important to limit qualifying investors to those who have an established record of successful investments in start-up entities. DHS believes that such a record would include, during the 5-year period immediately preceding the filing of the parole application, one or more investments in other start-up entities in exchange for equity or convertible debt comprising a total of no less than \$600,000. *See* final 8 CFR 212.19(a)(5)(i). DHS will require monetary commitments, rather than non-monetary commitments such as credit for in-kind value (e.g., credit for services), given the difficulty of valuing such commitments and the potential for fraud and abuse. The applicant would also need to show that, subsequent to such investment by the investor, at least 2 such entities each created at least 5 qualified jobs or achieved at least \$500,000 in revenue with average annualized revenue growth of at least 20 percent. *See* final 8 CFR 212.19(a)(5)(ii).

As described in greater detail above, these criteria are intended to ensure that investors are bona fide and thus protect the integrity of the parole process under this rule. They are also intended to ensure that a qualifying investment serves as a strong and reliable indicator of the start-up entity's substantial potential for rapid growth and job creation, which is relevant to assessing whether granting parole to an entrepreneur is justified by significant public benefit. DHS declines to adopt a special provision for regional centers approved to participate in the EB-5 visa program. Although such centers are not categorically excluded from the definition of "qualified investor" under this rule, they would need to meet all the same criteria as any other qualified investor.

## 12. Qualified Jobs

### a. Qualifying Employee

*Comments:* Two commenters recommended that DHS broaden the definition of the term "qualifying employee." One commenter stated that the term should include any individual authorized to work in the United States, regardless of immigration status, to avoid creating a conflict for employers who are prohibited from discriminating based on an individual's citizenship or immigration status. Another commenter advocated for the inclusion of independent contractors in the definition of qualifying employee.

*Response:* DHS declines to expand the definition of qualifying employee, which already includes a U.S. citizen, a lawful permanent resident, or other immigrant lawfully authorized to be employed in the United States, who is not an entrepreneur of the relevant start-up entity or the parent, spouse, brother, sister, son, or daughter of such an entrepreneur. *See* final 8 CFR 212.12(a)(7). DHS believes that creating jobs for these individuals is more likely to provide a significant public benefit given their stronger ties to the United States. Similarly, DHS believes that entrepreneurs and start-up entities that create positions for employees are more likely to provide a significant public benefit than those who rely only on arrangements with independent contractors. Such arrangements would generally have a weaker nexus to the start-up entity, may not have been created as a direct result of the start-up entity's activities, and could be more difficult to validate. Nothing in this rule either supersedes or conflicts with nondiscrimination laws enacted under the Immigration Reform and Control Act (IRCA).<sup>18</sup> Under existing law, it would generally be an unfair immigration-related employment practice for an entity to discriminate against someone authorized to work in the United States because of that person's national origin or, in the case of a "protected individual," citizenship status. *See* 8 U.S.C. 1324b(a) (generally prohibiting such practices, subject to specific exceptions, and defining "protected individual" to include U.S. citizens, lawful permanent residents, and certain other immigrants). This rule does not permit any such otherwise prohibited practices. Instead, it uses the creation of jobs for U.S. citizens, permanent residents, and other authorized immigrants as one indication of the

benefit created by an entrepreneur's start-up entity.<sup>19</sup>

### b. Full-Time Employment

*Comments:* Several commenters said that the rule should have a more flexible definition of "full-time employment." One commenter said that the definition of the term should not require the job to be filled for at least a year and should include job-sharing arrangements. Another commenter recommended that the definition of full-time employment include combinations of part-time positions.

*Response:* DHS declines to expand the definition of full-time employment to include jobs filled for less than a year by a qualifying employee, job-sharing arrangements, and combinations of part-time jobs. DHS believes that the creation of long-term and full-time positions is a more reliable indicator that an entrepreneur's start-up entity is continuing to yield significant public benefit. Jobs filled for less than a year could be temporary or seasonal, thus limiting the duration and impact of the benefit. Additionally, including job-sharing or combinations of part-time positions could significantly complicate adjudications. The final rule, moreover, already reduces by half the threshold number of jobs to qualify for a re-parole period, making it all the more reasonable to require that each of such jobs be full-time positions as part of the criteria for ensuring that granting parole to an international entrepreneur is justified by significant public benefit.<sup>20</sup>

## 13. Material Change

*Comment:* One commenter recommended that the final rule expressly exempt from the definition of "material change" transitions that are typical within start-ups, such as a company's (1) pivoting its products or services; (2) bringing on board a significant round of funding that could dilute the entrepreneur's ownership interest; (3) changing the role of a founder to meet the needs of the growing company; or (4) by virtue of a foreseeable stock or asset acquisition, executing a merger into or with a related or unrelated entity, or some other form of corporate restructuring. A few

<sup>19</sup> It is important to note that job creation during the initial period of parole is not the only way to demonstrate the start-up entity's continued substantial potential for rapid growth and job creation. *See* final 8 CFR 212.19(c)(2)(ii)(A), (c)(2)(ii)(C), and (c)(2)(iii).

<sup>20</sup> As explained earlier, job creation during the initial period of parole is not the only way to demonstrate the start-up entity's continued substantial potential for rapid growth and job creation. *See* final 8 CFR 212.19(c)(2)(ii)(A), (c)(2)(ii)(C), and (c)(2)(iii).

<sup>18</sup> Public Law 99-603 section 102, 100 Stat. 3359 (Nov. 6, 1986); INA section 274B.

commenters recommended that DHS clarify what constitutes a “material change” given the rapidly evolving nature of start-ups.

*Response:* DHS appreciates the concerns expressed by commenters regarding the material change definition in the NPRM. This final rule reflects changes that help clarify what constitutes a material change, with the understanding that start-up entities are likely to experience a variety of transitions as part of their legitimate development and growth. DHS disagrees, however, that all of the events listed by commenters should be specifically exempted from the definition of material change. Some changes to the start-up entity can clearly impact the determination of whether the entrepreneur provides, or will continue to provide, a significant public benefit to the United States. It is essential to the rule’s integrity that such material changes are clearly defined and reported to DHS. In the final rule, DHS has outlined those changes that DHS believes are critical to the continuing eligibility of the entrepreneur to be granted parole based on a significant public benefit to the United States. Specifically, the final rule maintains that the following changes are material: Any criminal charge, conviction, plea of no contest, or other judicial determination in a criminal case concerning the entrepreneur or start-up entity; any complaint, settlement, judgment, or other judicial or administrative determination concerning the entrepreneur or start-up entity in a legal or administrative proceeding brought by a government entity; any settlement, judgment, or other legal determination concerning the entrepreneur or start-up entity in a legal proceeding brought by a private individual or organization other than proceedings primarily involving claims for damages not exceeding 10 percent of the current assets of the entrepreneur or start-up entity; a sale or other disposition of all or substantially all of the start-up entity’s assets; the liquidation, dissolution, or cessation of operations of the start-up entity; and the voluntary or involuntary filing of a bankruptcy petition by or against the start-up entity. DHS has revised the definition of “material change” to include the cessation of the entrepreneur’s qualifying ownership interest in the start-up entity.

DHS recognizes that not all changes to the ownership structure of a start-up entity constitute a change of such significance that it would reasonably affect the outcome of the determination of whether the entrepreneur provides, or

continues to provide, a significant public benefit to the United States. DHS has revised the final rule to limit material change regarding ownership changes only to “a significant change with respect to ownership and control of the start-up entity.” For example, a significant change with respect to ownership and control of the start-up entity may include a transfer of equity in the start-up entity that results in an owner or owners not previously identified on the Application for Entrepreneur Parole (Form I-941) collectively acquiring a controlling stake in the entity. DHS recognizes that achieving a significant round of funding for the start-up entity during the initial parole period may often constitute the very qualifying investment that renders the entrepreneur eligible for a re-parole period under this rule’s significant public benefit test, despite diluting the entrepreneur’s ownership interest. While DHS will make these determinations on a case-by-case basis, DHS does not anticipate that such significant changes with respect to ownership and control of the start-up entity will often result in termination of parole. A full vetting of new investors with a significant ownership interest, however, can provide DHS with additional insights into the start-up entity’s activities in the United States and will help DHS ensure the entrepreneur is continuing to provide a significant public benefit to the United States. In the future, DHS may issue additional guidance on the scope of such significant changes in ownership interest if deemed necessary.

DHS believes these changes are sufficient to clarify the definition of “material change” in regulation and to provide entrepreneurs with sufficient detail about the kinds of changes that could impact their eligibility and must be reported. Given that this is a new and complex process, DHS will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

#### *E. Application Requirements*

##### 1. Application for Entrepreneur Parole

*Comments:* One commenter supported the Application for Entrepreneur Parole (Form I-941), and called it “ideal” because without the form applicants must attempt to list information on existing application forms that do not specifically relate to entrepreneurs. Another commenter requested that the application process resemble the Canadian express entry immigration system and be simplified

so that the assistance of an attorney is not required.

*Response:* DHS agrees with the comment that the Form I-941 is beneficial for capturing information specific to parole requests filed under this rule. DHS declines to model the application process for parole under this rule after the Canadian express entry program as that program is a points system designed to manage applications for permanent residence under certain Canadian federal economic immigration programs.<sup>21</sup> DHS has attempted to develop the Form I-941 to be as simple as possible for applicants while capturing sufficient information to enable adjudicators to make appropriate case-by-case decisions under the statutory and regulatory requirements for parole.

##### 2. Submissions of Documentary/ Supporting Evidence

*Comment:* Two commenters expressed concern that the evidentiary requirements were excessive and that start-up entities operating in “stealth-mode” would not be able to provide letters or media articles. Both commenters suggested that evidence of a significant capital investment from a qualified investor should be sufficient to demonstrate the potential for rapid growth and job creation.

*Response:* As an initial matter, DHS recognizes there may be legitimate reasons for operating a start-up in a manner that does not attract significant public attention. In part for this reason, this final rule extends the definition of start-up entity to include entities formed within the 5 years immediately preceding the filing date of the applicant’s initial parole request. DHS believes that start-up entities that are seeking to operate without significant public attention will generally have sufficient time to emerge from that status prior to the parole application.

DHS agrees with the commenters that evidence of having received substantial investment from a qualified investor may be sufficient to establish that the start-up entity has the potential for rapid growth and job creation (one factor in making parole determinations under this rule). See 8 final CFR 212.19(b)(2)(ii)(B)(1). DHS understands that other evidence that may be required to establish eligibility for parole consideration under this rule, including whether the applicant is well-positioned to advance the entity’s business, may not be a matter of public record. DHS believes, however, that even an entrepreneur operating a company in

<sup>21</sup> <http://www.cic.gc.ca/english/express-entry/>.



“stealth mode” should generally be able to provide such evidence for purposes of satisfying the requirements of this rule. Indeed, for entrepreneurs to be paroled under this rule, they must persuade adjudicators, based on the totality of the evidence, that they will provide a significant public benefit.

### 3. Application Requirements of Spouses and Minor Children

*Comment:* DHS received a few comments supporting the provision in the proposed rule allowing the spouse and children of an entrepreneur granted parole under this rule to also apply for and be granted parole in the United States in order to accompany or ultimately join the entrepreneur. One commenter also supported the proposal to allow the spouse, if granted parole, to obtain employment authorization in the United States in order to work and help support the entrepreneur’s family.

*Response:* DHS agrees with these comments. Each spouse or child seeking parole must independently establish eligibility for parole based on significant public benefit (or, alternatively, for urgent humanitarian reasons), and that the individual merits a favorable exercise of discretion. In a case in which an entrepreneur has been granted parole based on significant public benefit under this rule, DHS may consider granting parole to the entrepreneur’s spouse and children who provide a significant public benefit by maintaining family unity and thereby further encouraging the entrepreneur to operate and grow his or her business in the United States—and to provide the benefits of such growth to the United States.

Under this final rule, spouses of entrepreneur parolees who wish to obtain employment authorization must apply for an EAD pursuant to 8 CFR 274a.12(c)(34), consistent with current parole policy that allows parolees to apply for employment authorization. DHS agrees with the commenter that allowing spouses of entrepreneurs to apply for work authorization may alleviate a significant portion of the potential economic burdens that entrepreneurs and their families may face, such as paying for education expenses for their children, and to ensure that they satisfy the condition on their parole that they maintain household income that is greater than 400 percent of the Federal poverty line, as they grow and develop their start-up entities. Moreover, extending employment authorization to the spouse may further incentivize an international entrepreneur to bring a start-up entity to the United States—along with new jobs,

innovation, and growth—rather than create it in another country.

### 4. Other Comments on Application Requirements

*Comment:* One commenter asked that DHS clarify the application procedures for Canadians and whether they may apply at the border or whether they must visit a U.S. consulate prior to requesting to be paroled at a U.S. port of entry.

*Response:* Canadians and applicants from other countries may apply for parole under this rule while inside or outside of the United States. If the applicant’s parole request is approved, the applicant would request to be paroled by Customs and Border Protection at a U.S. port of entry after arriving from outside the United States. Canadian nationals who will be appearing at a U.S. port of entry directly from Canada will not have to visit a U.S. consulate prior to appearing at the port of entry and requesting that CBP grant parole. Canadian nationals who will not be appearing at a U.S. port of entry directly from Canada, and will instead be travelling to the United States from another country abroad to request a grant of parole may, similar to other applicants, have to visit a U.S. consulate first in order to obtain travel documentation (e.g., a boarding foil) that allows the individual to travel to a U.S. port of entry. In all cases, however, the individual must have an approved Form I-941 before the individual may appear at the port-of-entry to request a grant of parole.

### F. Parole Criteria and Conditions

#### 1. Minimum Investment

*Comment:* Numerous commenters—including advocacy groups, law firms, associations, and individual commenters—argued that the proposed rule’s minimum investment criterion for the initial parole period would set too high an eligibility bar for many high-potential entrepreneurs. Citing a range of different kinds of evidence, several commenters argued that the proposed \$345,000 threshold represented significantly more capital than is actually needed by most start-ups initially and would unnecessarily exclude from consideration some entrepreneurs whose entities would create significant public benefit in the United States.

*Response:* In response to public comments, DHS is reducing the proposed minimum investment of \$345,000 to \$250,000 in the final rule. See 8 final CFR 212.19(b)(2)(ii)(B)(1). Multiple public comments

recommended setting the threshold at \$250,000, and DHS’s further analysis of seed and angel investment data indicates that this level is reasonable. As is described more fully in the “Volume Projections” subsection of the “Statutory and Regulatory Requirements” section of this final rule, DHS’s analysis of investments received by a set of new firms that graduated from startup accelerator programs revealed that the median seed investment was \$250,000.<sup>22</sup> Following the intent of this final rule to increase and enhance entrepreneurship, innovation, and job creation in the United States, DHS determined that investment amounts that entrepreneurs would need to meet to be considered for parole under this rule should be more in line with typical early investment rounds, rather than the higher investment levels typical of later rounds. In each individual case, DHS must be persuaded that granting parole would provide a significant public benefit and that the person requesting parole merits a favorable exercise of discretion.

*Comment:* One commenter stated that there should not be a minimum investment amount and suggested that the rule instead establish minimum revenue amounts. Several other commenters suggested that evidence of rapid revenue growth should be a standalone eligibility criterion for the initial parole period under 8 CFR 212.19(b)(2)(ii).

*Response:* DHS disagrees with the suggestion that there should not be a minimum investment amount. Establishing a minimum investment amount based on available data provides a clear and predictable benchmark for how an applicant may demonstrate that a start-up entity has substantial potential for rapid growth and job creation (one factor in making parole determinations under this rule). If international entrepreneurs are unable to meet the threshold investment amount but have received some qualified investments or qualified government awards or grants, they may alternatively qualify for parole consideration under this rule if they partially meet the threshold criteria and provide “other reliable and compelling evidence of the start-up entity’s substantial potential for rapid growth and job creation.” See final 8 CFR 212.19(b)(2)(iii).

<sup>22</sup> The data utilized by DHS is provided publicly by SeedDB: <http://seed-db.com/accelerators>, as well as the Angel List: <https://angel.co/>, and the Angel Capital Association (ACA): <https://www.angelcapitalassociation.org/>.

DHS disagrees with the suggestion that evidence of rapid revenue growth or generation of a certain amount of revenue should be a separate criterion under 8 CFR 212.19(b)(2)(ii). In setting threshold criteria, DHS intends to identify reliable indicators of a start-up entity's substantial potential for rapid growth and job creation and, ultimately, of the significant public benefit that a grant of parole would provide in an individual case. DHS does not believe that revenue should be the sole external validation factor as compared to substantial funding from qualified U.S. investors and government entities for initial parole applications. DHS reiterates, however, that a start-up entity's revenue may be taken under consideration, both under the "alternative criteria" test and as part of the totality of evidence relevant to whether the grant of parole in an individual case would be justified by significant public benefit and the person requesting parole deserves a favorable exercise of discretion. See 8 CFR 219.2(b)(2)(iii), 219.2(c)(2)(B)(iii).

*Comment:* Several individual commenters recommended that the investment threshold be based upon the type of business activity.

*Response:* In an effort to provide a reasonable level of simplicity and predictability in the final rule, DHS decided to utilize a single investment threshold rather than several amounts based on the type of business activity. DHS believes that determining multiple investment thresholds based on business activity or industry would be unduly complicated, making adjudications more labor-intensive and increasing processing times. DHS believes that using a single investment threshold, backed by available data, is a reasonable approach and provides a clearer benchmark for applicants, investors, and adjudicators.

*Comment:* Some commenters provided input on the requirement that funding be received within the preceding 365 days. A CEO roundtable agreed that the \$345,000 threshold was an appropriate amount, but questioned the 365-day requirement, recommending that the rule be changed to require that only 65 percent of the investment to have occurred within the last 365 days. A trade association and a joint submission from a professional association and a non-profit organization recommended that the investment occur within a 3-year window. As an alternative, the trade association stated that some of a start-up entity's capital that would otherwise count toward the qualified investment amount should do so even if its ultimate

receipt by the start-up entity is contingent upon the approval of parole.

*Response:* DHS is revising the proposed requirement that the substantial investment be received within the 365 days immediately preceding the filing of the application for initial parole. The final rule increases this period from 12 months (365 days) to 18 months. DHS made this change based on feedback that it often takes longer than 12 months for a start-up to secure and receive investment funding. This revised requirement still ensures that a qualified investor or government entity has recently validated (within 18 months) the start-up entity's potential for rapid growth and job creation. With respect to the comment suggesting that DHS accept funding contingent upon approval of parole toward the qualified investment amount, DHS believes that funds contingent on the occurrence of a future event, such as a grant of parole to the entrepreneur, would not satisfy the general criteria in 8 CFR 212.19(b)(2)(ii). DHS notes, however, that such funds may be considered under the alternative criteria in 8 CFR 212.19(b)(2)(iii) if the entrepreneur partially meets one or both of the criteria in 8 CFR 212.19(b)(2)(ii)(B), since DHS may consider such contingent funds as other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation. Given that this process is a new and complex one, DHS has decided to take an incremental approach and will consider the suggested modification in the future after assessing the implementation of the rule and its impact on operational resources.

## 2. Minimum Government Grants or Awards

*Comment:* Several commenters argued that DHS should require less than \$100,000 to meet the eligibility criteria based on a start-up entity's receipt of government grants and awards. An individual commenter said that most government grants were well beneath the \$100,000 minimum threshold in the proposed rule. Another individual commenter recommended a \$50,000 government grant threshold. By contrast, one commenter stated that the \$100,000 minimum investment for government grants and awards is too low to start a meaningful business and suggested increasing the amount to \$500,000 or more. Several commenters stated that the \$100,000 grant threshold aligns with the timing of the Federal Small Business Innovation Research

(SBIR)<sup>23</sup> and Small Business Technology Transfer (STTR) awards and dollar amounts.

*Response:* DHS declines to make the suggested changes to the minimum government grant or award threshold. In light of the range of comments received on increasing or decreasing the minimum grant amount, DHS believes its proposed minimum grant amount is reasonable. Because government entities regularly evaluate the potential of U.S. businesses, the choice to provide a significant award or grant to a particular start-up entity will often be a strong indicator of that start-up's substantial potential for growth and job creation. Additionally, because government entities are by definition formed to serve the public, the choice by such an entity to fund a particular business generally indicates the government entity's independent assessment that the business's operations would provide a significant public benefit—and can be a strong indicator of a start-up entity's substantial potential for rapid growth and job creation. The specific \$100,000 minimum government funding threshold identified in this final rule is based in part on the phase that seed funding awards ("Phase I" awards) from the Federal SBIR/STTR program are generally below \$150,000.

## 3. Initial Parole Alternative Criteria

*Comment:* Several commenters offered suggestions for the factors to be considered by DHS under the rule's alternative criteria for the initial parole period, such as adding a metric for number of users or customers of the entrepreneur's start-up entity, the start-up entity's social impact, and the start-up entity's national scope or location in a low- or middle-class neighborhood. Other commenters proposed the following factors: The applicant's academic degree; participation in or training from a start-up accelerator; prior success as demonstrated by market share from patented innovations, annual sales volume, or job creation; and

<sup>23</sup> The Small Business Innovation Research (SBIR) program is coordinated by the Small Business Administration to seed capital for start-up businesses. It is designed to stimulate technological innovation among small private-sector businesses, and it is the largest source of seed capital in the United States for technology driven start-ups, funding between 5,000 and 7,000 projects a year. The "first phase" award is an innovation grant made for initial eligibility and corresponds to the start-up of the commercial business and proof of "concept phase"—the average award amounts vary by department, but most SBIR Phase I awards are made at or below \$150,000. The Phase I awards are geared towards financing the startup of the private commercial entity and also the innovation and research and development (R&D) that the enterprise undertakes.

demonstrated success using alternative funding platforms.

*Response:* DHS agrees with these suggestions. DHS may consider the following additional types of evidence, among others, as factors under the alternative criteria for those applicants who partially satisfy 8 CFR

212.19(b)(2)(ii):

- number of users or customers;
- revenue generated by the start-up entity;
- social impact of the start-up entity;
- national scope of the start-up entity;
- positive effects on the start-up entity's locality or region;
- success using alternative funding platforms, including crowdfunding platforms;
- the applicant's academic degrees;
- the applicant's prior success in operating start-up entities as demonstrated by patented innovations, annual revenue, job creation, or other factors; and
- selection of the start-up entity to participate in one or more established and reputable start-up accelerators or incubators.

With respect to start-up accelerators and incubators, DHS expects to evaluate them on several relevant factors, including years in existence, graduation rates, significant exits by portfolio start-ups, significant investment or fundraising by portfolio start-ups, and valuation of portfolio start-ups.

DHS understands that some applicants will be able to establish that their start-up entity is likely to grow rapidly and create jobs based on other factors beyond only the amount of capital investment or government funding received, which is why DHS has not limited the types of evidence that may be considered under the alternative criteria at 8 CFR 212.19(b)(2)(iii) for those who only partially meet the initial threshold criteria at 8 CFR 212.19(b)(2)(ii)(B).

*Comment:* One commenter suggested linking the rule's application to applications for other initiatives, such as National Minority Supplier Development Council Certification and, when applicable, Minority Women Based Entrepreneur Certification.

*Response:* DHS appreciates the commenters' suggestions but declines to adopt these factors as evidence of substantial potential for rapid business growth or job creation. Nothing in this rule prohibits or discourages entrepreneurs from participating in initiatives or certification processes designed to help promote more diverse and inclusive entrepreneurship. DHS does not believe, however, that such initiatives and certifications

independently provide sufficient external validation that a start-up entity has the substantial potential for rapid growth or job creation and meets the "significant public benefit" requirement under this rule. Evidence that the start-up is involved with certain initiatives in the public interest can, however, be considered a positive factor in determining whether an entrepreneur merits a grant of parole as a matter of discretion. Given that this is a new and complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

*Comment:* One commenter said the term "reliable and compelling evidence" in proposed 8 CFR 212.19(b)(2)(iii), with respect to the start-up entity's substantial potential for rapid growth and job creation, is too vague and should be elaborated on further in the regulatory text.

*Response:* DHS disagrees with the commenter's suggestion to elaborate further in 8 CFR 212.19(b)(2)(iii) on the type of evidence that may be submitted and considered as reliable and compelling. DHS believes that this alternative criterion should be flexible so as not to restrict the types of evidence that may be submitted and relied upon to determine if the start-up entity has substantial potential for rapid growth and job creation. DHS believes that such flexibility is important given the case-by-case nature of these discretionary parole determinations. An applicant for parole under this rule who does not meet the threshold capital investment or government funding criteria in 8 CFR 212.19(b)(2)(ii)(B) may submit any evidence that the applicant believes is reliable and compelling to support the claim that the applicant's start-up entity has substantial potential for rapid growth and job creation. DHS, after reviewing the application and all of the evidence submitted in support of the application, will make a determination as to whether the applicant is eligible for parole consideration under the relevant statutory and regulatory standards, and as to whether the person seeking parole merits a favorable exercise of discretion.

*Comment:* One commenter asserted that securing an investment from a U.S. investor or obtaining a U.S. government grant or award is not a viable option for most people.

*Response:* DHS believes that qualified investments or government funding are appropriate factors to consider when assessing the ability of a start-up entity to achieve rapid growth and job creation

(one factor in making parole determinations under this rule). DHS, however, understands that some start-up entities with the potential to yield significant public benefit may have legitimate economic or strategic reasons to not pursue or accept capital investment or government funding at the levels set forth in 8 CFR 212.19(b)(2)(ii)(B). Therefore, DHS has provided in the rule an alternative criterion for further consideration of those applications where the applicant only partially satisfies the capital investment or government funding thresholds, but provides additional reliable and compelling evidence that establishes the substantial potential of the start-up entity for rapid growth and job creation.

*Comment:* A commenter suggested that, instead of focusing on capital investment and job creation criteria, DHS should focus on whether the start-up entity would be in industries in traded sectors. The commenter proposed that the following industries would qualify: Manufacturing, software publishers, Internet publishing, and research and development services.

*Response:* While DHS recognizes the benefits of increased exports to the U.S. economy, it declines to limit eligible start-up entities to traded sectors, since start-up entities in a much wider set of industries can yield significant public benefit to the United States through rapid growth and job creation.

*Comment:* A commenter requested that DHS form an advisory group of industry experts to recommend alternative criteria.

*Response:* DHS afforded an opportunity for notice and comment on the NPRM and expressly sought proposals for alternative criteria from the public. DHS does not believe that forming a new advisory group is necessary at this time.

*Comment:* One commenter suggested that the term "rapid growth" should be determined based on factors pertaining to the start-up entity's industry, normal business growth in the industry, geographic area, and the amount of investment in the entity. The commenter also recommended that the term "substantial potential" take into account the start-up entity's particular geographic area rather than a national scale.

*Response:* While the industry- and geography-specific factors suggested by the commenter may be taken into consideration by DHS as part of the totality of the circumstances for a given application, DHS believes that the general and alternative eligibility criteria provided in the final rule are

sufficient to determine if a start-up entity has the substantial potential for rapid growth and job creation, and provide a more predictable framework by which these parole applications will be adjudicated than would a more mechanical and unduly rigid consideration of the variables suggested by the commenter.

#### 4. Re-parole Criteria

##### a. Minimum Investment or Grants/Awards

*Comment:* Several commenters discussed the proposed re-parole eligibility criteria at 8 CFR 212.19(c)(2)(ii)(B)(1), namely that the applicant's start-up entity has received at least \$500,000 in qualifying investments, qualified government grants or awards, or a combination of such funding, during the initial parole period. Most commenters argued that this funding level was unduly high, especially given the duration of the initial parole period.

*Response:* DHS declines to adjust the \$500,000 funding threshold. See final 8 CFR 212.19(c)(2)(ii)(B)(1). DHS believes that \$500,000 is a reasonable level for re-parole. An industry report on startups shows the median seed investment round for the first half of 2016 was \$625,000, which rose from \$425,000 in 2015. This figure is valuable because it includes seed rounds for firms that participate with accelerators and that often start out with investment rounds below \$100,000.<sup>24</sup> The median for angel group seed investments is reported at \$620,000 as the annual average over 2013–2015, which rose sharply to \$850,000 in 2015 from a median of \$505,000 from the previous two years. Venture capital round sizes are even larger, as the 2014 median round size for both seed and startup stage venture rounds was \$1,000,000.

DHS has also increased the length of the initial parole period from 24 months to 30 months. This change will allow entrepreneurs additional time to seek and receive qualified investments or government funding, to meet the re-parole criteria. If an entrepreneur is unable to meet the minimum funding

criterion, moreover, he or she may still be eligible for re-parole based on revenue generated or jobs created. See final 8 CFR 212.19(c)(2)(ii)(B)(2) and (3). Under the final rule, entrepreneurs partially meeting the threshold re-parole criteria may alternatively qualify “by providing other reliable and compelling evidence of the start-up entity’s substantial potential for rapid growth and job creation.” Final 8 CFR 212.19(c)(2)(iii).

##### b. Minimum Annual Revenue

*Comment:* Several commenters discussed the proposed re-parole criterion at 8 CFR 212.19(c)(2)(ii)(B)(3), which establishes an eligibility threshold when the applicant's start-up entity has reached at least \$500,000 in annual revenue and averaged 20 percent in annual revenue growth during the initial parole period. Most commenters suggested alternative approaches, arguing that start-ups are often legitimately focused on the development of an innovative product or service, and not on generating early revenue. Another commenter stated that the revenue criterion is reasonable.

*Response:* DHS declines to adjust these criteria. See final 8 CFR 212.19(c)(2)(ii)(B)(1). DHS chose \$500,000 in revenue and 20 percent annual revenue growth as threshold criteria because, after consulting with SBA, DHS determined these criteria: (1) Would be reasonable as applied across start-up entities regardless of industry or location; and (2) would serve as strong indications of an entity's potential for rapid growth and job creation (and that such entity is not, for example, a small business created for the sole or primary purpose to provide income to the owner and his or her family). As noted, DHS has also increased the length of the initial parole period from 24 months to 30 months. This change will allow entrepreneurs additional time to meet the minimum revenue threshold for re-parole. If an entrepreneur is unable to meet the minimum revenue requirement, he or she may still be eligible under the minimum investment or job creation criteria. See final 8 CFR 212.19(c)(2)(ii)(B)(1) and (2). Under the final rule, entrepreneurs partially meeting the threshold re-parole criteria may alternatively qualify “by providing other reliable and compelling evidence of the start-up entity’s substantial potential for rapid growth and job creation.” Final 8 CFR 212.19(c)(2)(iii).

*Comment:* An individual commenter suggested that DHS should include in the rule a criterion for user growth, rather than revenue growth, as many

start-ups focus more on growing their number of users in their early years.

*Response:* DHS declines to include user growth as a stand-alone criterion for establishing eligibility for re-parole. DHS, however, may consider user growth as a factor when evaluating an entrepreneur's eligibility under the alternative criteria provision. The list of factors provided in the preamble to the proposed rule was intended only to illustrate the kinds of factors that DHS may consider as reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

As noted in the NPRM, DHS is not defining in regulation the specific types of evidence that may be deemed “reliable and compelling” at this time, because DHS seeks to retain flexibility as to the kinds of supporting evidence that may warrant the Secretary's exercise of discretion in granting parole based on significant public benefit. DHS believes, however, that such evidence would need to be compelling to demonstrate that the entrepreneur's presence in the United States would provide a significant public benefit. DHS will evaluate on a case-by-case basis whether such evidence—in conjunction with the entity's substantial funding, revenue generation, or job creation—establishes that the applicant's presence in the United States will provide a significant public benefit during a re-parole period.

*Comment:* An individual commenter suggested that the minimum annual revenue threshold for re-parole be set as just enough to sustain the entrepreneur's salary and continue business operations.

*Response:* The final rule states that the start-up entity must be of a type that has the substantial potential to experience rapid growth and job creation, including through significant levels of capital investment, government awards or grants, revenue generation, or job creation during the re-parole period. These factors are intended to help DHS identify the types of start-up entities that are most likely to provide a significant public benefit, while excluding entities without such potential—such as a business with limited growth potential created by an entrepreneur for the sole or primary purpose of providing income to the entrepreneur and his or her family.<sup>25</sup> Because this latter type of business is less likely to experience rapid growth

<sup>24</sup> The report on the seed median is published as a newsletter by Crunchbase and is found at: <https://techcrunch.com/2016/09/07/crunchbase-sees-rise-in-average-seed-round-in-2016/>. The Angel group median round size is obtained from the Angel Resource Institute's annual (2015) “Halo Report,” found at <http://angelresourceinstitute.org/reports/halo-report-full-version-ye-2015.pdf>. The venture capital figures are obtained from the Ernst and Young Venture Capital Insights Report (4th quarter 2014) and are found at: [http://www.ey.com/Publication/vwLUAssets/Venture\\_Capital\\_Insights\\_4Q14\\_-\\_January\\_2015/%24FILE/ey-venture-capital-insights-4Q14.pdf](http://www.ey.com/Publication/vwLUAssets/Venture_Capital_Insights_4Q14_-_January_2015/%24FILE/ey-venture-capital-insights-4Q14.pdf).

<sup>25</sup> Erik Hurst & Benjamin Wild Pugsley, “What Do Small Businesses Do?” (Aug. 2011), available at [http://www.brookings.edu/~media/files/programs/es/bpea/2011\\_fall\\_bpea\\_papers/2011\\_fall\\_bpea\\_conference\\_hurst.pdf](http://www.brookings.edu/~media/files/programs/es/bpea/2011_fall_bpea_papers/2011_fall_bpea_conference_hurst.pdf).

and job creation, DHS believes it is unlikely that the entrepreneur of such a business would be able to meet the significant public benefit requirement for a grant of parole. Establishing a minimum annual revenue threshold for re-parole that would, by definition, cover only an entrepreneur's salary and continue business operations would not likely help identify whether an entrepreneur's activity in the United States would provide a significant public benefit. DHS therefore declines to adopt the commenter's suggestion.

#### c. Minimum Jobs Created

*Comment:* Several commenters discussed the proposed re-parole criterion at 8 CFR 212.19(c)(2)(ii)(B)(2), which establishes an eligibility threshold for applicants whose start-up entities have created at least 10 qualified jobs within the start-up entities during the initial parole period. Most commenters argued that this job creation requirement was unduly high or that the time period for compliance was too short.

*Response:* Based on comments received, DHS has lowered the job creation criterion for re-parole from 10 to 5 qualified jobs. See final 8 CFR 212.19(c)(2)(ii)(B)(2). DHS agrees with commenters that requiring 10 jobs to satisfy this criterion may be unduly high for many start-ups, even those with demonstrated substantial potential for rapid growth and job creation. DHS believes that the creation of 5 qualifying jobs during the initial period of parole is sufficient to determine that the start-up entity continues to have substantial potential for rapid growth and job creation, particularly in light of the substantial capital investment, government funding, or other reliable and compelling evidence that supported the initial parole determination. In each case, DHS must be persuaded that re-parole is justified by significant public benefit and that the person seeking re-parole merits a favorable exercise of discretion. As discussed elsewhere in this preamble, DHS has also extended the initial period of parole from 2 years to 30 months, in order to allow additional time for start-up entities to grow, obtain additional substantial funding, generate substantial revenue, or create jobs. See 8 CFR 212.19(c)(2)(iii).

#### d. Re-Parole Alternative Criteria

*Comment:* One commenter suggested that DHS should consider taxes paid by a start-up entity as a criterion for re-parole, leaving the task to DHS to define the threshold of the amount and type of taxes paid.

*Response:* DHS declines to adopt the commenter's suggestion. DHS believes that a start-up entity would have to generate a significant level of revenue or job creation (which are already criteria under this rule) to meet any separate, standalone tax-based threshold. Any such additional criterion would therefore be unlikely to be particularly probative in determining whether re-parole is justified by significant public benefit or the person seeking re-parole merits a favorable exercise of discretion. DHS therefore declines to include the payment of taxes as a stand-alone eligibility criterion.

*Comment:* A commenter suggested that if DHS lowers the funding and job creation thresholds for re-parole, there should be no need for alternative criteria.

*Response:* While DHS did reduce the job creation threshold for re-parole in the final rule, DHS believes that parolees should have the flexibility to present other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation. Examples of such evidence are provided above, in the discussion on alternative criteria for the initial parole period. DHS believes that it is important to retain such flexibility in the final rule, consistent with the case-by-case nature of these parole determinations. DHS, therefore, has not adopted the commenter's suggestions.

#### 5. Authorized Periods of Parole

*Comment:* Several commenters discussed the initial 2-year parole period at 8 CFR 212.19(d)(2). Most commenters argued that the 2-year period was unduly short, as start-ups with significant potential for rapid growth and job creation may require more time to meet re-parole eligibility requirements. Some commenters suggested having a 3-year initial period of parole and a 2-year period of re-parole. Other commenters suggested a range for initial parole from 3 to 5 years. A number of comments discussed the overall duration of the parole periods, the majority of which advocated for longer periods ranging from 6 to 10 years in total. Some of these commenters based the need for an extended parole period on the typical duration of the start-up growth path from seed funding to venture capital financing to exit (through an initial public offering or a merger or acquisition).

*Response:* Based on the comments received, DHS is changing the maximum periods for initial parole and re-parole to 30 months (2.5 years) each, for a total maximum parole period

under this rule of up to 5 years. The additional time for the initial parole period will provide entrepreneurs with more time to receive additional qualified investments or government funding, increase revenue, or create qualified jobs sufficient to meet the eligibility criteria for an additional period of parole. While this change does reduce the length of the re-parole period, DHS believes that this approach is necessary to provide additional time during the initial period of parole while maintaining the same maximum overall parole period of 5 years. DHS further believes that a 5-year total maximum parole period is consistent with the amount of time successful start-up entities generally require to realize rapid growth and job creation potential. Moreover, an entrepreneur of a start-up entity that is almost 5 years old when the parole application is filed would have the possibility to obtain up to 5 years of parole, which would allow the entity to realize its rapid growth and job creation potential by the time it is 10 years old—and to provide those benefits in the United States.<sup>26</sup> DHS retains the discretion to provide any length of parole to an applicant, including a period shorter than 30 months where appropriate. DHS also notes that although USCIS would designate an appropriate initial parole period upon approval of the Application for Entrepreneur Parole, CBP would retain its authority to deny parole to an applicant or to modify the length of parole authorized by USCIS upon issuing parole at the port of entry, consistent with CBP's discretion with respect to any advance authorization of parole by USCIS.

<sup>26</sup> Estimates based on the Census Bureau Business Dynamics Statistics suggest that on average 55 percent of new firms survived after 3 years, but 80 percent of the firms that survived 3 years also made it through 5 years. Dane Stangler and Jared Konczal "Give me your entrepreneurs, your innovators: Estimating the Employment Impact of a Startup Visa", Ewing Marion Kauffman Foundation (Feb. 2013), available at [http://www.kauffman.org/-/media/kauffman\\_org/research%20reports%20and%20covers/2013/02/startup\\_visa\\_impact\\_final.pdf](http://www.kauffman.org/-/media/kauffman_org/research%20reports%20and%20covers/2013/02/startup_visa_impact_final.pdf); "CrunchBase Reveals: The Average Successful Startup Raises \$41M, Exits at \$242.9M," Techcrunch.com (Dec. 14, 2013), available at <http://techcrunch.com/2013/12/14/crunchbase-reveals-the-average-successful-startup-raises-41m-exits-at-242-9m/>; see also TruBridge Capitol Partners, *Why the 'Next Billion Dollar Startup' Is not Always the Next IPO*, Forbes, Apr. 15, 2015, available at <http://www.forbes.com/sites/truebridge/2015/04/15/why-next-billion-dollar-startup-not-always-next-ipo/> ("From 2001–2004, the average age of a company at its public exit was 5.4 years. . . . From 2009–2012, the average age was 7.9.").

## 6. Limitation on Number of Entrepreneurs

*Comment:* Several commenters addressed 8 CFR 212.19(f) in the proposed rule, which states that no more than three entrepreneurs may be granted parole based on the same start-up entity. Most commenters on this provision recommended that DHS increase the number of entrepreneurs, with suggestions to increase the maximum number to 4 or 5. Several other commenters, including a trade association and a professional association, supported the proposed rule's limit of 3 entrepreneurs obtaining parole under this rule based on the same start-up entity. An individual commenter stated that DHS should allow for additional entrepreneurs to qualify for parole based on the same start-up entity, not only at the time of application but also at a later date, asserting that it is very common for technology companies to introduce multiple co-owners over time that are key personnel vital to the operations of the start-up entity.

*Response:* DHS appreciates the comments regarding this limitation and recognizes that some start-ups may initially have more than 3 founders or owners. After reviewing all comments, DHS declines to increase the number of entrepreneurs permitted to request parole related to the same start-up entity, and will retain the current limit of no more than 3 eligible entrepreneur applicants per start-up entity. See final 8 CFR 212.19(f). As an initial matter, DHS believes it would be difficult for a larger number of entrepreneurs associated with the same start-up entity to each meet the eligibility criteria and comply with the conditions on parole while ultimately developing a successful business in the United States. A higher number of entrepreneurs associated with the same start-up entity may affect the start-up's ability to grow and succeed, and may even result in the startup's failure, thus preventing the goals of the parole process under this rule from being realized.<sup>27</sup> Imposing a limit on the number of entrepreneurs who may be granted parole based on the same start-up entity is thus consistent with ensuring that each entrepreneur's

parole will provide a significant public benefit.

The limitation, moreover, will help strengthen the integrity of the international entrepreneur parole process in various ways. Among other things, limiting the number of individuals who may be granted parole under this rule in connection with the same start-up entity will provide an additional safeguard against an entity being used as a means to fraudulently allow individuals to come to the United States. Such a limit diminishes, for example, the incentive to dilute equity in the start-up entity as a means to apply for parole for individuals who are not bona fide entrepreneurs. Finally, DHS clarifies that the rule does not require that additional entrepreneurs, up to 3 entrepreneurs per start-up entity, apply for parole based on the same start-up entity at the same time.

## 7. Income-Related Conditions on Parole

*Comment:* Several commenters discussed the proposed rule's provision requiring that entrepreneurs paroled into the United States must maintain a household income that is greater than 400 percent of the Federal poverty line for their household size, as defined by the Department of Health and Human Services. Many of these commenters discussed the financial difficulties faced by start-ups and argued that the income requirements were unduly high or suggested other alternatives. The majority of commenters on this issue stated that entrepreneurs in start-up endeavors typically do not take a salary or take a minimal salary in the early years. Several commenters recommended lowering this income threshold, with many suggesting lowering it to 100 percent, while others suggested alternatives of 125 percent, 200 percent, or 250 percent of the Federal poverty level. An individual commenter recommended that DHS institute a minimum yearly income requirement of \$80,000, while another individual commenter stated that DHS should adopt a more nuanced approach that takes into account factors like standard of living, unemployment rates, and economic growth by state. Other commenters recommended that DHS allow for other types of compensation, in the form of benefits or rewards, in addition to salary to satisfy the income-related conditions on parole. Another individual commenter stated that DHS should use the income threshold already established by the Affidavit of Support,<sup>28</sup> which is set at 125 percent

above the poverty guidelines. Lastly, one commenter said the "significant public benefit" determination should not just be applied to entrepreneurs who meet a particular income or wealth criterion, but should be liberally applied to all entrepreneurs who are seeking to build and grow a business.

*Response:* DHS appreciates the concerns raised by these commenters, but declines to adopt the commenter's suggestion to eliminate or alter the income-related condition on parole. Establishing this income-related condition on parole is consistent with the Secretary's discretionary authority to grant parole "under conditions as he may prescribe." INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A). As stated in the NPRM, DHS established this income threshold to ensure that applicants seeking parole under this rule will have sufficient personal economic stability to make significant economic and related contributions to the United States. Those policy goals remain valid and are appropriate in guiding the decision to retain the requirement that the household income of an entrepreneur requesting parole under this rule be greater than 400 percent of the Federal poverty line.

Under this rule, DHS will take steps to ensure that each grant of parole will provide a positive net benefit to the economy of the United States, consistent with the statutory framework authorizing parole only for significant public benefit absent urgent humanitarian issues. In addition to considering all the other positive evidence—from job creation to investment to growth—DHS includes the income threshold as an additional safeguard that the entrepreneur and his or her family will not be eligible to draw upon Federal public benefits or premium tax credits under the Health Insurance Marketplace of the Affordable Care Act. Furthermore, Secretary Johnson indicated in his memorandum titled "Policies Supporting U.S. High-Skilled Business and Workers" that such thresholds would be created so that individuals would not be eligible for these public benefits or premium tax credits in light of the purpose of the policy.<sup>29</sup>

DHS emphasizes that the funding amounts received by a start-up entity from governmental sources or from

show that they have adequate means of financial support and are not likely to rely on the U.S. government for financial support.

<sup>29</sup> Memorandum from Jeh Johnson, DHS Secretary, Policies Supporting U.S. High-Skilled Business and Workers 4 (Nov. 20, 2014), at [https://www.dhs.gov/sites/default/files/publications/14\\_1120\\_memo\\_business\\_actions.pdf](https://www.dhs.gov/sites/default/files/publications/14_1120_memo_business_actions.pdf).

<sup>27</sup> Max Marmor, Bjoern Lasse Herrmann, Ertan Dogrultan, Ron Berman, *Startup Genome Report Extra on Premature Scaling*, Startup Genome Report: Premature scaling v 1.2 (Mar. 2012 ed.) (explaining that "hiring too many people too early" in a start-up's development is one of several reasons that most start-ups fail), available at [https://s3.amazonaws.com/startupcompass-public/StartupGenomeReport2\\_Why\\_Startups\\_Fail\\_v2.pdf](https://s3.amazonaws.com/startupcompass-public/StartupGenomeReport2_Why_Startups_Fail_v2.pdf).

<sup>28</sup> Affidavits of Support, filed using Form I-134 or I-864, are required for certain immigrants to

qualified investors in order to meet the rule's eligibility thresholds are distinct from the possible sources of salary payments to the individual entrepreneur. Nothing in this rule prevents a start-up entity from raising higher funding levels than the minimum parole eligibility thresholds, and from a wider set of funders than those in the rule's definitions of qualified investors and government entities. DHS intends for the eligibility criteria for parole to be useful independent validation tools for assessing the significant growth and job creation potential of the start-up entity. While there is certainly validity to the arguments made by some of the commenters that many entrepreneurs do not take large salaries, choosing instead to re-invest available funds back into the start-up entity or to take other forms of non-cash compensation, DHS must establish criteria that protect the overall policy goals of this rule in accordance with the requirements of the INA. The income-related requirements offer a clear and predictable mechanism for DHS to have a strong measure of confidence that the entrepreneur and his or her family, while paroled into the United States under this rule, will be net positive contributors to the American economy.

#### 8. Reporting of Material Changes

*Comment:* Several commenters discussed the proposed requirement that entrepreneurs report any material changes during a parole period to DHS by submitting a new application for parole. Most commenters argued that such a requirement would be onerous given the constantly changing nature of start-ups. A law firm argued that requiring entrepreneurs to report and reapply when there are pending actions against the start-up entity or entrepreneur would be unfair, as both are entitled to due process, and suggested a reporting requirement only if an adverse judgment were issued. An individual commenter stressed that a \$1,200 fee to report every material change would create a major financial burden for entrepreneurs.

*Response:* DHS recognizes that the nature of start-up entities involves constant change. DHS also appreciates the concerns regarding the administrative and financial burden placed on entrepreneurs by additional filings. DHS believes, however, that the revised definition of material change in the final rule will help to clarify the situations in which the entrepreneur must notify the agency of material changes, and thus limit the administrative and financial burdens on the entrepreneur. Specifically, DHS

understands that start-ups may have frequent ownership changes over the course of successive funding rounds, and thus has revised the definition of "material change" regarding ownership changes to cover only those that are "significant" in nature. Clarifying the scope of the material change definition also limits the reporting requirement, which should help reduce the anticipated burden on entrepreneurs. DHS also emphasizes that the rule requires notification of pending actions only in the context of a criminal case or other action brought by a government entity, while actions brought by private individuals or entities are not considered "material changes" until a settlement, judgment, or other final determination is reached. DHS does not believe that the material change reporting requirement under this rule will impact an individual's due process or would otherwise be unfair. DHS believes, however, that it is important for an entrepreneur granted parole under this rule to immediately inform USCIS if certain actions are brought against the entrepreneur or his or her start-up entity.

*Comment:* One commenter recommended that the process of addressing material changes would be improved if DHS were to implement a policy similar to the "deference" policy it applies in the EB-5 investor program. Such a policy provides that DHS will defer to prior determinations regarding certain documentary evidence used to establishing program eligibility requirements absent fraud, misrepresentation, a mistake of law or fact, or a material change.

*Response:* As discussed above, DHS decided to narrow and clarify the definition of "material change" in order to address commenters' concerns about reporting burdens. In the absence of specific suggestions, DHS could not ascertain from this comment what aspect of the EB-5 deference policy could be applied under this rule. DHS believes it is important for this rule to provide mechanisms, including the requirement to report material changes, to ensure that parole continues to be justified by significant public benefit in each particular case.

*Comment:* A joint submission from a professional association and a non-profit organization stated that, where a material change filing is mandated by the rule, the entrepreneur should only be required to file an update with USCIS, instead of being required to re-file an entire parole or re-parole application.

*Response:* As explained above, while DHS appreciates that a new filing may

appear burdensome to the entrepreneur, DHS believes that a new filing is necessary in order to re-evaluate the entrepreneur's eligibility when such material changes occur. Material changes, by their definition, may affect the entrepreneur's ability to demonstrate that the start-up entity has potential for rapid growth and job creation, and whether the entrepreneur will continue to provide a significant public benefit to the United States. Therefore, at present, the entrepreneur must file a new application to allow DHS the opportunity to determine the entrepreneur's continued eligibility for parole. Given that this is a new and complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after it has assessed the implementation of the rule and its impact on operational resources.

#### 9. Other Comments on Parole Criteria and Conditions

*Comment:* Several comments expressed concern that the rule did not require that the entrepreneur receive prevailing wages for their work, with some commenters expressing concern that the only wage requirements relate to the Federal Poverty Level.

*Response:* DHS appreciates commenters' concerns regarding prevailing wages. Unlike some employment-based visa classifications, however, the intention of this parole process is not to address labor shortages in the United States. Rather, it is to encourage international entrepreneurs to create and develop start-up entities with high growth potential in the United States. DHS believes that requiring the parolee to maintain a household income of greater than 400 percent of the Federal Poverty Level adequately ensures that he or she will have sufficient personal economic stability to provide a significant public benefit to the United States through entrepreneurial activities.

*Comment:* One commenter recommended that DHS should not require an applicant's start-up entity to receive investment prior to the initial application for parole; that DHS should recognize cash infusions during the growth period of a start-up entity as eligibility criteria for re-parole; and that at the end of the initial parole period, if the venture is deemed successful, no additional funding milestones should be required for re-parole eligibility.

*Response:* DHS appreciates the comment but declines to revise the rule as suggested. DHS believes that the alternative criteria provided in this rule to determine if the start-up entity has



substantial potential for rapid growth and job creation provide sufficient flexibility for those entrepreneurs who may have received amounts of qualified investments or government funding that are less than those required to satisfy the general criteria for parole consideration under this rule. The determination that the entity has substantial potential for rapid growth and job creation will be made based on the evidence in the record at the time the parole application is adjudicated, rather than the possibility that the entity may receive cash infusions at some point in the future. If cash infusions from various sources are received by the start-up entity during the period of initial parole, evidence of such cash infusions may be taken into consideration if the entrepreneur applies for re-parole. DHS, however, does not believe that cash infusions into the start-up entity during the initial parole period will independently suffice to establish that the entity continues to have the significant potential for rapid growth and job creation. Infusions of cash, as a general matter, do not have the same validating qualities as do evidence of additional investment from qualifying investors, grants or awards from qualifying government entities, significant revenue growth, or job creation.

*Comment:* One commenter asserted that entrepreneurs who have left their start-up entity should not have their parole status immediately revoked. The commenter suggested that DHS issue guidance and options for entrepreneurs who leave their start-up entity but have contributed to the significant public benefit of the United States. A similar comment recommended that individuals be able to remain in the United States under parole and qualify for re-parole if a second start-up meets the requirements of the rule. Another related comment argued that entrepreneurs whose start-up entities fail should be given a second chance, in order to account for the dynamism and uncertainty inherent in new businesses.

*Response:* DHS appreciates the comments but declines to adopt the commenters' suggestions. As a matter of statutory authority, once, in the opinion of DHS, the purpose of parole has been served, parole should be terminated. See INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A). DHS emphasizes that the purpose of granting parole under this rule is to allow an entrepreneur to grow a start-up entity in the United States with substantial potential for rapid growth and job creation, by working in an active and central role for the entity. Accordingly, DHS will not continue

parole for entrepreneurs who are no longer actively working in a central role with the start-up entity that served as the basis for the initial parole application. The individual's activity through a new start-up entity, however, could serve as a basis for a new grant of parole if all requirements for such parole are met.

*Comment:* One commenter suggested that DHS should utilize the same methodology for granting parole for entrepreneurs as defined in a proposed nonimmigrant visa classification in a Senate bill, S. 744, 113 Cong. section 4801(2013).

*Response:* DHS appreciates the comment but declines to adopt the commenter's suggestion. Under this rule, DHS has identified a process for implementing the Secretary's existing statutory authority to grant parole consistent with section 212(d)(5) of the INA. DHS does not believe it is advisable to import in this rule the standards from unenacted legislation focused on nonimmigrant visas rather than discretionary grants of parole.

#### G. Employment Authorization

##### 1. Automatic Employment Authorization Upon Parole

*Comment:* One commenter suggested that if employment authorization were deemed incident to parole, rather than through a follow-up application, then the regulations governing employment verification would need to be amended to permit employment by the parolee and spouse without an EAD.

*Response:* DHS agrees that the employment verification provisions of the regulations should be appropriately revised. In this final rule, and as proposed, DHS is revising the employment eligibility verification regulations by expanding the foreign passport and Form I-94 document combination described at 8 CFR 274a.2(b)(1)(v)(A)(5) to include Forms I-94A containing an endorsement that an individual is authorized to work incident to parole. This document combination was previously acceptable only for certain nonimmigrants authorized to work for a specific employer incident to status pursuant to 8 CFR 274a.12(b), which the final rule amends to include those paroled into the United States as entrepreneurs under this rule. See final 8 CFR 274a.12(b)(37).

However, in this final rule, and as proposed, only the entrepreneur parolee is accorded employment authorization incident to his or her parole. See final 8 CFR 274a.12(b). Given the basis for parole, it is essential to limit any delays

in the entrepreneur's own employment authorization. Such delays could create difficulties for the entrepreneur's operation of the start-up entity, as he or she would be prohibited from working until work authorization was approved, and would frustrate the very purpose for paroling the entrepreneur into the United States. As an entrepreneur's spouse would not be coming for the same kind of specific employment purpose, DHS does not believe there is a similar need to provide him or her work authorization incident to parole. Instead, this rule adds a new provision making the spouse of an entrepreneur parolee eligible to seek employment authorization. See final 8 CFR 274a.12(c)(34). Based on this provision and 8 CFR 274a.13(a), an entrepreneur's spouse seeking employment authorization under this rule would need to file an Application for Employment Authorization (Form I-765) with USCIS in accordance with the relevant form instructions.

*Comment:* One commenter expressed concern that the proposed employment authorization provision is too narrow in scope. The commenter stated that DHS should clarify that employment with an entity that is under common control as the start-up entity, such as a subsidiary or affiliate, would be permissible.

*Response:* Under the final rule, the entrepreneur parolee's employment authorization is limited to the specific start-up entity listed on the Application for Entrepreneur Parole, Form I-941. This limitation helps ensure that the entrepreneur's work is consistent with the purposes for which parole was granted, especially since parole applications will be evaluated based in part on the activities and performance of that particular start-up entity. DHS appreciates that there are certain circumstances in which some flexibility could further the purpose of encouraging entrepreneurship, innovation, economic growth, and job creation in the United States. Given that this is a new process however, DHS has decided to take an incremental approach and will consider potential modifications in the future after assessing the implementation of the rule.

*Comment:* One commenter stated that difficulties obtaining a work visa have caused many entrepreneurs to move out of the United States.

*Response:* DHS agrees with the commenter's statement. While this rule does not address all of the difficulties that entrepreneurs may face, or make legislative changes that only Congress can make, DHS believes it will encourage international entrepreneurs

to develop and grow their start-up entities—and provide the benefits of such growth—in the United States. Entrepreneurs paroled into the United States under this rule will be authorized to work for the start-up entity for the duration of the parole (and any re-parole) period.

## 2. Spousal Employment

*Comment:* Several commenters, including a business incubator, asserted that spouses should be granted employment authorization and argued that spouse employment authorization will entice more entrepreneurs to come to the United States. Several other commenters stated that, in order to attract the best entrepreneurial talent, spouses of entrepreneur parolees should automatically receive work authorization incident to status without the need to apply separately.

*Response:* DHS agrees with commenters that extending employment authorization to spouses of entrepreneur parolees is important to help attract entrepreneurs to establish and grow start-up entities in the United States. For reasons provided above, however, DHS disagrees that these spouses must be provided with employment authorization incident to their parole. Instead, these spouses may seek employment authorization under 8 CFR 274a.12(c)(34).

*Comment:* A few commenters stated opposition to permitting employment authorization for the spouses of international entrepreneurs.

*Response:* DHS disagrees with the commenters' opposition to allowing an entrepreneur's spouse to apply for employment authorization. Permitting spouses to seek employment authorization is an important aspect of the rule's intent to attract international entrepreneurs who may provide a significant public benefit by growing their start-up entities in the United States.

*Comment:* One commenter objected to spousal employment authorization unless it is restricted to the same new high-potential start-up entity that served as the basis for the parole.

*Response:* DHS disagrees with the suggestion that spousal employment should be authorized only for employment with the start-up entity that served as the basis of parole for the entrepreneur. Nothing in this rule prevents people married to each other from applying for parole associated with the same start-up entity. But DHS believes that it is not appropriate or necessary to limit the employment of an entrepreneur's spouse to that entity. Making those spouses eligible to seek

employment from a broader range of employers can further the central purpose of the rulemaking—encouraging international entrepreneurs to develop and grow their start-up entities within the United States and provide the benefits of such growth to the United States. It may also encourage entrepreneurs to create more jobs outside the family through the start-up entity, furthering the benefits provided to others in the United States. DHS therefore declines to revise the rule as suggested.

## H. Comments on the Parole Process

### 1. Ability of Individuals To Qualify for Parole Under This Rule

*Comment:* Two individual commenters asked what kind of immigration status or visa an international entrepreneur should maintain in order to be eligible to apply for parole under this rule. The commenters expressed concern about the types of activities that would need to be conducted in the United States prior to a parole application in order to establish a business, obtain funds from investors, and otherwise qualify for the parole under this rule. These commenters also expressed concern about requiring prior investment as a condition for parole, and that investors would be hesitant to make such an investment in a start-up entity if the entrepreneur lacked an immigrant or nonimmigrant visa. A professional association stated that, since parole does not constitute formal admission to the United States, it will likely be very difficult for international entrepreneurs without formal immigration status to enter into long-term contracts, raise significant investment capital, and employ people.

*Response:* This final rule aims to encourage international entrepreneurs to create and develop start-up entities with high growth potential in the United States, which are in turn expected to facilitate research and development in the country, create jobs for U.S. workers, and otherwise benefit the U.S. economy. Under this final rule, an international entrepreneur may request parole in accordance with the form instructions. The final rule provides that individuals seeking initial parole under this program must present themselves at a U.S. port of entry to be paroled into the United States; there is no requirement that an international entrepreneur currently be in the United States or maintain any prior immigration status. DHS notes, however, that under the statute governing parole authority, individuals

who have already been admitted to the United States are ineligible to be considered for parole inside the United States because only applicants for admission are eligible to be considered for parole. See INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A); see also INA section 235(a)(1), 8 U.S.C. 1225(a)(1) (describing “applicants for admission”). Individuals who have been admitted in a nonimmigrant classification, and are currently in the United States pursuant to that admission, may not be paroled, even if they have overstayed their admission, unless they first depart the United States.

DHS appreciates that international entrepreneurs may face many challenges in starting and growing a business in the United States, including attracting investment capital or government grants or awards. DHS disagrees with the premise, however, that qualifying investors will be very reluctant to make a qualifying investment in a start-up entity that is wholly or partially owned by an individual that will be seeking a grant of parole under this rule. DHS believes that there are a myriad of factors that go into a decision to invest significant funds in a start-up entity. While the underlying immigration status, or lack thereof, of the start-up entity's owner(s) may be a factor presenting a degree of additional risk, DHS believes that this rule will effectively mitigate some of that risk by providing a known framework under which certain significant public benefit parole requests will be reviewed and adjudicated. This final rule provides investors and entrepreneurs with greater transparency into the evaluation process and manner in which such requests will be reviewed, so that those individuals and entities can weigh the various risks and benefits that might apply to the particular investment decision being considered. Given that this is a new and complex process, DHS has decided to take an incremental approach and will consider potential modifications in the future after assessing the implementation of the rule.

### 2. Waiver for Entrepreneurs Presently Failing To Maintain Status

*Comment:* An individual commenter stated that international entrepreneurs already in the United States should be able to receive a waiver in order to establish eligibility for parole under this rule if they do not have a valid prior immigration status. Another commenter suggested that immigration status violations, such as unauthorized employment, should not be grounds for denying parole under this rule and, if parole is granted, any prior

unauthorized employment that was used to meet the requirements for parole should be disregarded for purposes of any future immigration applications.

*Response:* As discussed above, eligibility for parole under INA section 212(d)(5), 8 U.S.C. 1182(d)(5), is not wholly dependent upon an individual's current immigration status. Unauthorized employment or a prior status violation will not necessarily preclude an individual from qualifying for parole under this rule. However, the fact that an entrepreneur has worked without authorization, is out of status, or not legally present in the United States would be considered in determining whether DHS should grant parole under its discretionary authority. All requests for a discretionary grant of parole are adjudicated on a case-by-case basis and ultimately determined by evaluating all positive and negative factors.

DHS will not adopt the commenter's suggestion to disregard, for purposes of any future immigration applications, any prior unauthorized employment that was used to meet the requirements for parole. DHS believes that such a provision would require a statutory change, as eligibility for certain benefits is barred by statute if the applicant previously worked without authorization.<sup>30</sup>

### 3. Relationship Between Parole and Various Nonimmigrant Visa Classifications

#### a. Pathway for Current Nonimmigrants To Use Entrepreneur Parole

*Comment:* Some commenters expressed concern that it would be challenging for foreign students, recent graduates of U.S. universities, and other nonimmigrants presently in the United States to meet this rule's requirements for parole consideration under the constraints of their current visas. These commenters said that the rule should allow these individuals a realistic and clear pathway to easily utilize parole, and should clarify that potential applicants currently in the United States in nonimmigrant status will not be violating their existing visa status when taking the necessary steps to establish eligibility for significant public benefit parole. One commenter requested that students in F-1 nonimmigrant status and eligible to work on Curricular Practical Training (CPT) or Optional Practical Training (OPT) should become eligible for parole under the rule if they founded a start-up and raised \$100,000 in capital.

*Response:* DHS appreciates that some entrepreneurs who are present in the United States and who might otherwise qualify for parole under this program may be unable to engage in certain activities given the limitations placed on their nonimmigrant status, making it difficult, for example, for them to raise significant capital for a start-up entity. DHS, however, disagrees with the commenters' assertion that individuals present in the United States in F-1 nonimmigrant status will be unable to meet the requirements for parole under this program, such as starting a business and raising significant investment, without violating their F-1 nonimmigrant status. For example, an individual in F-1 status who has obtained OPT employment authorization may start and work for his or her own business in the United States. The OPT employment, and thus the business, must relate to the F-1 nonimmigrant's program of study and can occur either before (pre-completion OPT) or after the completion of a program of study (post-completion OPT).<sup>31</sup> Additional requirements apply to F-1 nonimmigrants who are otherwise eligible for a STEM OPT extension, such as establishing that their STEM OPT employer will have a valid employer-employee relationship with the F-1 OPT nonimmigrant, but those additional requirements do not pertain to the initial 12-month OPT period, and in any event do not present an absolute bar against entrepreneurial activities. DHS believes that it is certainly realistic that an F-1 nonimmigrant in the United States can start a business during his or her OPT period, and during that time can take steps to obtain significant investment in the start-up entity, which the individual may then rely upon if applying for parole under this rule. DHS declines to adopt the commenters' suggestion to include in this rule a blanket provision stating that potential applicants currently in the United States in nonimmigrant status will not be violating their existing status when taking steps to establish eligibility for parole. Such changes would pertain to the statutory and regulatory limitations placed on various nonimmigrant classifications and are outside the scope of this rule.

DHS believes that this final rule provides a realistic and clear option for certain entrepreneurs to actively grow their qualifying start-up entity in the United States. As discussed below, parole is not a nonimmigrant status, and individuals present in the United States

in a nonimmigrant status will not be able to change status or otherwise be granted parole without first departing the United States and appearing at a U.S. port of entry for inspection and parole. Under this final rule, however, an individual present in the United States in a nonimmigrant status may apply for and obtain an approval of the Application for Entrepreneur Parole (Form I-941). Filing and obtaining approval of a Form I-941 application under this rule will not, by itself, constitute a violation of the individual's nonimmigrant status. After approval of the Form I-941 application, if the individual decides to rely upon parole to actively grow his or her business in the United States, the individual will need to appear at a U.S. port of entry for a final parole determination to allow him or her to come into the United States as a parolee.

This final rule already provides appropriate criteria under which all applications will be reviewed, including those submitted by any F-1 nonimmigrants. As indicated in this final rule, one basis on which an individual may be considered for parole under this rule is if he or she has raised at least \$250,000 in investment capital from a qualifying investor (and meets certain other criteria). Individuals who raise a substantial amount of capital from a qualifying investor, but less than \$250,000, may still qualify for and be granted parole under other criteria identified in the rule—including the receipt of a qualifying government grant or award or other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

#### b. Switching Between Nonimmigrant Status and Parole

*Comment:* Several commenters raised questions or provided suggestions regarding switching from a nonimmigrant status to parole, or from parole to a nonimmigrant status. Specifically, one commenter asked what her status would be if she were in the United States as an H-4 nonimmigrant, authorized to work pursuant to an EAD, but nevertheless pursued parole under this rule. Another commenter suggested that DHS should include a provision in this rule that expressly allows someone to switch from nonimmigrant status to parole, and from parole to nonimmigrant status, similar to DHS's policy to terminate and restore the H-1B or L-1 status of certain individuals who have temporarily departed the United States but came back using an advance parole document that was

<sup>30</sup> See, e.g., INA section 245(c), 8 U.S.C. 1255(c).

<sup>31</sup> <https://studyinthestates.dhs.gov/training-opportunities-in-the-united-states>.

issued based on a pending Form I-485 application for adjustment of status.

*Response:* DHS declines to adopt a provision in this rule allowing individuals to change between nonimmigrant status and parole while in the United States. An individual who is present in the United States as a nonimmigrant based on an inspection and admission is not eligible for parole without first departing the United States and appearing at a U.S. port of entry to be paroled into United States. See INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A). Moreover, an individual who has been paroled into the United States cannot change to nonimmigrant status without leaving the United States, as INA section 248, 8 U.S.C. 1258, only permits individuals who are maintaining nonimmigrant status to change to another nonimmigrant status. If an individual who has been paroled into the United States under this rule has a petition for nonimmigrant classification approved on his or her behalf, he or she would have to leave the United States and pursue consular processing of a nonimmigrant visa application before seeking to return to the United States.

#### c. Entrepreneur Pathways and Entrepreneur Parole

*Comment:* One commenter stated that the international entrepreneur parole rule should complement and not supplant prior USCIS policy pertaining to entrepreneurs, including those reflected on the USCIS Entrepreneur Pathways Web site.<sup>32</sup> The commenter, while expressing concerns with aspects of existing policies pertaining to entrepreneurs and this rule, suggested that if an entrepreneur cannot qualify for parole under this rule, USCIS should encourage the entrepreneur to seek a visa associated with his or her start-up entity under the existing immigrant or nonimmigrant visa system. Specifically, the commenter suggested that the final rule should expressly include an amendment to the H-1B regulations to allow approval of an H-1B petition under the policies articulated on the Entrepreneur Pathways Web site, and that USCIS adjudicators should see an express statement in the final rule that, notwithstanding the existence of this rule, the H-1B visa remains available for working owners of start-up entities. The commenter noted that the USCIS Entrepreneur Pathways Web site also provides guidance for entrepreneurs to use other existing nonimmigrant visa classifications (e.g., L-1, O, and E visas) that could be more advantageous to the

entrepreneur than the parole rule, so adjudicators should continue to approve petitions in that spirit. The commenter asserted that the unique requirements under the parole rule, such as a threshold investment amount, should not be allowed to “bleed into and taint” the adjudicatory process for securing employment-based visas traditionally used by entrepreneurs.

*Response:* DHS appreciates the commenter’s suggestions, but the suggested changes to the H-1B regulations are outside the scope of this rulemaking. DHS agrees with the commenter that parole under this program is intended to complement, and not supplant, other options that may already exist for entrepreneurs under other immigrant and nonimmigrant visa classifications. This rule does not alter existing rules or policies regarding the ability of entrepreneurs to qualify for any immigrant or nonimmigrant status. This rule does, however, provide an additional avenue for entrepreneurs to consider when exploring options that may be available to them to grow a start-up entity in the United States.

#### 4. Travel Document Issuance

*Comment:* A commenter urged DHS to grant multiple-entry parole to foreign nationals so that they may travel internationally and return to the United States, as this is not explicit in the regulation. The commenter stated that this ability is essential to ensure that entrepreneurs can raise additional funds and market innovations worldwide. In addition, this commenter stated that some foreign nationals may begin their businesses and seek entrepreneur parole while in nonimmigrant status in the United States, such as in F-1 or H-1B nonimmigrant status (and thus seek to depart the United States with advance parole and then request parole from CBP upon their return to a U.S. port of entry). The commenter suggested that the regulation clarify how these foreign nationals will be able to return to the United States.

*Response:* DHS notes that individuals who have been admitted to the United States, such as those in nonimmigrant status, are not eligible to be granted parole unless they first depart the United States. DHS clarifies that any immigration status violations by any applicant for parole, including those related to their entrepreneurial efforts, will be taken into account as negative factors in the case-by-case determination of whether the applicant merits an exercise of discretion to grant parole, though they will not necessarily

prohibit the individual from obtaining a grant of parole under this rule.

DHS recognizes that international travel can be essential for the success of some start-up entities. Under existing law, an individual’s authorized period of parole ends each time he or she departs the United States. See 8 CFR 212.5(e)(1)(i). DHS may, however, authorize advance parole before departure and can specify that such authorization is valid for multiple uses. An entrepreneur granted advance parole would be able to leave the country, present himself or herself at a port of entry upon return, and request a subsequent grant of parole for the remaining period of his or her initially granted parole period. At such time, DHS must then inspect the individual and determine whether or not to grant parole into the United States.<sup>33</sup> If the individual is granted parole, he or she may only be paroled for up to the time initially granted. Any time spent outside the United States after the parole period is initiated will count against the total period of parole, so that the total time period of the parole period remains consistent with the date of initial parole granted by CBP.

#### 5. Parole in Place

*Comment:* Several commenters requested that DHS allow parole-in-place under this rule. Some of these commenters stated that parole-in-place should be added so that individuals already in the United States in a nonimmigrant status, such as H-1B or F-1 nonimmigrant status, can apply for and be granted parole under this rule without having to depart the United States. Several other commenters noted that DHS has the jurisdiction to allow parole-in-place for spouses or dependents, as they do for military family members, and that this could be applied to the International Entrepreneur Rule. Some commenters argued that the requirement to be out of the country to apply for parole under this rule puts an unnecessary financial burden on applicants who are already residing in the United States.

*Response:* DHS appreciates, but declines to adopt, the commenters’ suggestions that parole-in-place be allowed under this rule for individuals already in the United States in H-1B or F-1 nonimmigrant status. Only applicants for admission are eligible to

<sup>33</sup> This process is not appropriately described as “multiple-entry parole.” Parole does not constitute an admission to the United States, INA sections 101(a)(13)(B), 212(d)(5)(A), 8 U.S.C. 1101(a)(13)(B), 1182(d)(5)(A); and parole terminates upon the individual’s departure from the United States, 8 CFR 212.5(e)(1)(i).

<sup>32</sup> See <https://www.uscis.gov/eir>.

be considered for parole, thus precluding individuals who have already been admitted from being considered for parole inside the United States. *See* INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A); *see also* INA section 235(a)(1), 8 U.S.C. 1225(a)(1) (describing “applicants for admission”). Such individuals are not eligible for parole, regardless of whether they have overstayed their admission, unless they first depart the United States.

#### 6. Comments on Options After 5-Year Total Parole Period Ends

*Comment:* Many commenters provided views on the options available to entrepreneurs who have exhausted their up to 5 years of eligibility for parole under this rule. Some commenters were concerned that the rule does not provide a direct path to lawful permanent residence, which could limit the investment prospects for start-up entities. Other commenters were concerned that including such a path could exacerbate current immigrant visa backlogs and thus disadvantage those already in the queue for immigrant visa numbers.

A number of commenters were more broadly concerned that the overall uncertainty inherent in parole may discourage entrepreneurs from using this rule to start and grow their businesses in the United States. One particular commenter expressed concerns about an entrepreneur’s ability to demonstrate nonimmigrant intent for purposes of a visa that does not permit dual intent. Others wanted DHS to consider entrepreneurs who have completed a 5-year parole period, and whose start-ups continue to demonstrate growth, as eligible for an EB–2 immigrant visa with a National Interest Waiver based upon the economic benefit to the United States. Other commenters urged DHS to establish *prima facie* eligibility for lawful permanent residence based on 3 years of parole under this rule. Still others wanted assurance that an individual who is the beneficiary of an approved immigrant petition would keep his or her priority date for purposes of receiving lawful permanent residence if he or she were granted parole under this rule.

*Response:* DHS appreciates the wide range of comments about immigration options for entrepreneurs after the end of their authorized period or periods of parole under this rule. Nothing in this rule forecloses otherwise available options for international entrepreneurs who are granted parole. DHS further notes that this rule does not impact existing rules and policies pertaining to

retention of priority dates in the immigrant petition context. The rule does not, however, establish a direct path to lawful permanent residence by creating a new immigrant visa classification for international entrepreneurs, which could only be done by Congress.

As discussed in the NPRM, the entrepreneur and any dependents granted parole under this program will be required to depart the United States when their parole periods have expired or have otherwise been terminated, unless such individuals are otherwise eligible to lawfully remain in the United States. Such individuals may apply for any immigrant or nonimmigrant classification for which they may be eligible (such as classification as an O–1 nonimmigrant or lawful permanent residence through employer sponsorship). Individuals who are granted parole under this rule may ultimately be able to qualify for an EB–2 immigrant visa with a National Interest Waiver. If an entrepreneur is approved for a nonimmigrant or employment-based immigrant visa classification, he or she would generally be required to depart the United States and apply for a visa at a U.S. embassy or consulate abroad. As noted above, because parole is not considered an admission to the United States, parolees will be unable to apply to adjust or change their status in the United States under many immigrant or nonimmigrant visa classifications. DHS does not believe that merely being granted parole under this rule would prevent an individual from demonstrating nonimmigrant intent for purposes of obtaining a subsequent nonimmigrant visa for entry into United States. DHS believes that this rule presents sufficient clarity and predictability for many individuals who want to establish and grow their businesses in the United States, and will contribute significantly to economic growth and job creation here. Such positive outcomes may be relevant in the event that entrepreneurs granted parole under this rule later seek to apply for an existing nonimmigrant or immigrant visa.

#### I. Appeals and Motions To Reopen

*Comment:* Several commenters requested that applicants be allowed to file appeals or motions to reconsider adverse parole decisions. A business association requested that submissions of motions to reopen or motions for reconsideration result in uninterrupted employment authorization for the parolee.

*Response:* DHS appreciates but declines to adopt these suggestions.

DHS has concluded that granting a right of appeal following a decision to deny entrepreneur parole would be inconsistent with the discretionary nature of the adjudication and contrary to how DHS treats other parole decisions. The final rule also precludes applicants from filing motions to reopen or for reconsideration under 8 CFR 103.5(a)(1). DHS retains its authority and discretion, however, to reopen or reconsider a decision on its own motion as proposed. *See* final 8 CFR 212.19(d)(4). Applicants may alert DHS, through existing customer service channels, that they believe that a decision to deny parole was issued in error and include factual statements and arguments supporting such claims.

Because the determination to grant or deny a request for parole is discretionary, the parole process in this final rule may not be relied upon to create any right or benefit, substantive or procedural, enforceable at law or by any individual or other party in removal proceedings, in litigation with the United States, or in any other form or manner. Parole determinations would continue to be discretionary, case-by-case determinations made by DHS, and parole may be revoked or terminated at any time in accordance with the termination provisions established by this rule at 8 CFR 212.19(k). Parolees under this final rule would assume sole risk for any and all costs, expenses, opportunity costs, and any other potential liability resulting from a revocation or termination of parole. A grant of parole would in no way create any reliance or due process interest in obtaining or maintaining parole or being able to remain in the United States to continue to operate a start-up entity or for other reasons.

#### J. Termination of Parole

##### 1. Discretionary Authority To Revoke/ Terminate Parole

*Comments:* One commenter expressed concern that the basis for terminating parole is subjective, particularly with respect to reporting material changes. This commenter suggested that USCIS should limit such reporting to adverse judgments, since entrepreneurs and start-up entities are entitled to due process. Other commenters requested that USCIS adjudicators be specifically trained on entrepreneurship issues so that they can make the most informed decisions regarding parole.

*Response:* USCIS is committed to providing sufficient training on entrepreneurship issues for those adjudicators who will be assigned to adjudicating entrepreneur parole

requests. DHS does not believe that further revisions to the rule are necessary to protect against possible unfair or inconsistent determinations among adjudicators. By statute, parole decisions are discretionary and must be made on a case-by-case basis. This rule establishes transparent parameters for termination of parole, including automatic termination and termination on notice. Automatic termination applies at the expiration of parole, or upon written notification to DHS from the entrepreneur parolee that he or she is no longer employed by the start-up entity or no longer possesses the required qualifying ownership stake in the start-up entity. *See* final 8 CFR 212.19(k)(2). Termination on notice with an opportunity for the entrepreneur to respond is authorized by 8 CFR 212.19(k)(3). These bases for termination are tied to objective facts regarding eligibility for parole, thereby placing all parolees on the same footing.

The commenter expressed particular concern regarding terminations based on material changes. DHS believes that this concern is sufficiently addressed by the parameters set by this rule's definition of material change. Under this rule, material change means any change in facts that could reasonably affect the outcome of the determination whether the entrepreneur provides, or continues to provide, a significant public benefit to the United States. *See* final 8 CFR 212.19(a)(10). This rule provides further guidance by listing several examples illustrating material changes, including: Any criminal charge, conviction, plea of no contest, or other judicial determination in a criminal case concerning the entrepreneur or start-up entity; any complaint, settlement, judgment, or other judicial or administrative determination concerning the entrepreneur or start-up entity in a legal or administrative proceeding brought by a government entity; any settlement, judgment, or other legal determination concerning the entrepreneur or start-up entity in a legal proceeding brought by a private individual or organization other than proceedings primarily involving claims for damages not exceeding 10 percent of the current assets of the entrepreneur or start-up entity; a sale or other disposition of all or substantially all of the start-up entity's assets; the liquidation, dissolution or cessation of operations of the start-up entity; the voluntary or involuntary filing of a bankruptcy petition by or against the start-up entity; a significant change with respect to ownership and control of the start-up

entity; and a cessation of the entrepreneur's qualifying ownership interest in the start-up entity or the entrepreneur's central and active role in the operations of that entity. *See* final 8 CFR 212.19(a)(10).

## 2. Notice and Decision

*Comments:* A couple of commenters suggested that DHS provide notice and opportunity to respond before terminating parole.

*Response:* DHS agrees with the commenters that providing the entrepreneur parolee with notice and an opportunity to respond prior to termination is reasonable in certain scenarios, such as when grounds for termination require an assessment of the underlying case by the adjudicator. However, where no such assessment is required, DHS believes that automatic termination is appropriate. The NPRM provided for termination at DHS's discretion, including automatic termination in limited circumstances and termination on notice under a range of circumstances deemed appropriate by DHS. This rule finalizes that proposal without change. *See* final 8 CFR 212.19(k)(2) and (3). Under this rule, therefore, DHS will generally provide notice of termination and an opportunity to respond where it believes that:

(1) The facts or information contained in the request for parole were not true and accurate;

(2) The alien failed to timely file or otherwise comply with the material change reporting requirements in this section;

(3) The entrepreneur parolee is no longer employed in a central and active role by the start-up entity or ceases to possess the required ownership stake in the start-up entity;

(4) The alien otherwise violated the terms and conditions of parole; or

(5) Parole was erroneously granted.

Automatic termination will apply upon the expiration of parole or if DHS receives written notice from the parolee informing DHS that he or she is no longer employed by the start-up entity or no longer possesses the required qualifying ownership stake in the start-up entity. DHS believes that these bases for automatic termination clearly evidence that the entrepreneur no longer qualifies for parole under this rule; therefore, notice and opportunity to respond are unnecessary. Additionally, parole of the spouse or child of the entrepreneur will be automatically terminated without notice if the parole of the entrepreneur has been terminated. This rule also finalizes the provision indicating that the

decision to terminate parole may not be appealed, that USCIS will not consider a motion to reopen or reconsider a decision to terminate parole, and, upon its own motion, USCIS may reopen or reconsider a decision to terminate. *See* final 8 CFR 212.19(k)(4).

## 3. Other Comments on Application Adjudication and Parole Termination

*Comments:* Multiple commenters suggested an expedited or premium processing option for entrepreneur parole applicants. Some of these commenters suggested a maximum 30-day adjudication time period.

*Response:* While DHS appreciates the concern for timely adjudications, at this time DHS declines to include premium or expedited processing as part of the final rule. DHS may consider the possibility of premium processing or expedited processing after assessing implementation of the rule and an average adjudication time for processing requests for parole under this rule has been determined.

## K. Opposition to the Overall Rule

*Comment:* Multiple commenters expressed overall opposition to the rule, stating that there is no reason to add an additional parole process for highly trained and talented entrepreneurs when visa and residency pathways already exist, such as the O nonimmigrant visa, EB-5 immigrant visa, or EB-2 immigrant visa based on a National Interest Waiver. Other commenters asserted that the United States needs to limit immigration, not create more immigration programs. Several individual commenters argued that the U.S. Government should reform other visa programs, such as the H-1B nonimmigrant classification, and address the current immigrant visa backlog before creating more programs. Several individual commenters asserted that taxpayer money should be used on domestic issues, such as reviving the American economy, rebuilding infrastructure, promoting national security, and supporting veterans, rather than on administering a parole process for international entrepreneurs.

*Response:* DHS disagrees with the commenters' assertions that sufficient avenues for international entrepreneurs already exist. DHS believes that this final rule will, by further implementing authority provided by Congress, reduce barriers standing in the way of innovation and entrepreneurial activity that will benefit the U.S. economy.<sup>34</sup>

<sup>34</sup> Nina Roberts, *For foreign tech entrepreneurs, getting a visa to work in the U.S. is a struggle*, *The*

This final rule provides an avenue for innovative entrepreneurs to pursue their entrepreneurial endeavors in the United States and contribute to the U.S. economy. In the absence of this rule, these innovative entrepreneurs might be delayed or discouraged altogether in contributing innovation, job creation, and other benefits to the United States.

DHS also disagrees with the commenters' assertions that reforms should be made to the H-1B nonimmigrant classification and that the immigrant visa backlog should be addressed before this rule is finalized. Parole is an entirely separate option within the Secretary's authority to allow individuals to come to the United States on a case-by-case basis for urgent humanitarian reasons or significant public benefit. While DHS appreciates the commenters' sentiment that changes should be made in other contexts, the exact changes contemplated by the commenters are unclear, are outside the scope of this rulemaking, or would require congressional action.

DHS also disagrees with the assertion that taxpayer funds will be misallocated to process applications for parole under this final rule. Applicants for parole under this rule will be required to submit a filing fee to fully cover the cost of processing of applications.

#### L. Miscellaneous Comments on the Rule

##### 1. Additional Suggested Changes to the Rule

*Comments:* A number of commenters suggested additional changes to the final rule that are beyond the scope of this rulemaking. These comments proposed changes to the regulations governing certain nonimmigrant programs, namely: Employment of F-1 nonimmigrant students through Optional Practical Training (OPT); annual H-1B numerical limitations; "period of stay" duration for L-1 nonimmigrants starting a new office in the United States; and merging significant public benefit parole with the O-1 visa program. A commenter suggested providing Employment Authorization Documents or lawful permanent resident status to individuals who obtained their Master's degrees in the United States. Other commenters

suggested providing tax incentives to established U.S. corporations that would agree to mentor immigrant entrepreneurs, or establishing a system of compensation for certain senior citizens in the United States to mentor immigrant entrepreneurs. Other commenters recommended balancing parole for entrepreneurs with refugee admissions.

*Response:* DHS thanks commenters for these suggestions but declines to make changes to the rule as these comments are outside the scope of this rulemaking.

*Comment:* A joint submission from an advocacy group and professional association recommended that DHS consider parole for individuals who work in social services fields that do not command a high income or who might otherwise perform work in the national interest.

*Response:* This final rule is aimed at international entrepreneurs who will provide a significant public benefit to the United States—which could include entrepreneurs whose startup entities operate in the field of social services, so long as they meet the criteria for parole in this final rule. Furthermore, this rule does not limit the Secretary's broader authority to grant parole to other applicants for admission on a case-by-case basis for urgent humanitarian reasons or significant public benefit.

##### 2. Information/Guidance

*Comment:* One commenter recommended that DHS make parole data from the program publicly available.

*Response:* While DHS did not propose to disclose parole data related to this rule, DHS appreciates the commenter's suggestion, and may consider making such data publicly available after this rule is implemented.

*Comment:* Other commenters suggested that DHS provide additional guidance to those granted parole under this rule and to provide resources for small start-ups interested in applying for the rule.

*Response:* DHS will evaluate whether to provide additional guidance following publication of this final rule and an assessment of its implementation.

*Comment:* One commenter suggested that DHS add a provision to the rule for retrospective review, in order to analyze the effects of the rule's implementation.

*Response:* DHS agrees with the commenter's suggestion that the effects of the rule, after its implementation, should be reviewed; however, DHS does not believe adding a provision to the final regulatory text requiring such

review is necessary. DHS intends to review all aspects of this parole rule and process subsequent to its implementation and consistent with the direction of Executive Order 13563. Given that this is a new and complex process, DHS will consider potential modifications in the future after assessing the implementation of the rule and its impact on operational resources.

*Comment:* One commenter said these rules should serve as a guide, but that companies and entrepreneurs should be analyzed on case-by-case basis.

*Response:* DHS may grant parole on a case-by-case basis under this rule if the Department determines, based on the totality of the evidence, that an applicant's presence in the United States will provide a significant public benefit and that he or she otherwise merits a favorable exercise of discretion.

*Comment:* An individual commenter suggested that DHS should, as part of its assessment of parole applications under this rule, evaluate the performance of applicants' prior start-ups in their home countries.

*Response:* DHS agrees with the commenter and believes that the performance of applicants' prior start-ups in their home countries is the type of evidence already contemplated by the final rule both under the alternative criteria provisions and as part of the determination as to whether an applicant merits a favorable exercise of discretion. The alternative criteria allow an applicant who partially meets one or more of the general criteria related to capital investment or government funding to be considered for initial parole under this rule if he or she provides additional reliable and compelling evidence that his or her parole would provide a significant public benefit to the United States. Such evidence would need to serve as a compelling validation of the entity's substantial potential for rapid growth and job creation. DHS is not defining the specific types of evidence that may be deemed "reliable and compelling" at this time, as DHS seeks to retain flexibility as to the kinds of supporting evidence that may warrant DHS's exercise of discretion in granting parole based on significant public benefit.

##### 3. Comments Regarding the E-2 Nonimmigrant Classification

*Comment:* Several commenters submitted comments regarding the E-2 nonimmigrant classification. The majority supported the inclusion of E-2 businesses into the parole process under this rule. Several companies and an individual commenter further recommended that the rule should

Guardian, Sept. 14, 2014, available at <http://www.theguardian.com/business/2014/sep/14/foreign-tech-entrepreneurs-visa-us-struggle>; Amy Grenier, *Majority of U.S. Patents Granted to Foreign Individuals*, April 11, 2014, available at <http://immigrationimpact.com/2014/04/11/majority-of-u-s-patents-granted-to-foreign-individuals/> ("Because of the limitations of the H-1B visa program, and the lack of a dedicated immigrant visa for entrepreneurs or innovators, foreign inventors struggle with inadequate visa options that often prevent them from obtaining permanent residency.").



accommodate E-2 businesses already in the United States.

*Response:* The final rule lays out specific criteria for determining the kind of start-up enterprise that has substantial potential for job growth and job creation, and for assessing whether an individual entrepreneur's parole would be justified by significant public benefit. DHS believes it is unnecessary to identify these enterprises even more specifically than in this final rule. DHS notes that the rule does not prevent individuals who might otherwise qualify for an existing immigrant or nonimmigrant classification from applying for parole under this rule.

*Comment:* One commenter stated that the proposed rule is much more complicated than the E-2 nonimmigrant classification, and that DHS should incorporate elements of the E-2 program into this rule's parole process.

*Response:* DHS disagrees with the commenter's suggestion.<sup>35</sup> A grant of parole under this rule is based on a determination that the individual will provide a significant public benefit to the United States. Eligibility for E-2 nonimmigrant classification is based on different standards, and DHS believes that applying E-2 requirements would not suffice to meet the statutory requirements for parole and establish that an individual merits a favorable exercise of discretion. DHS therefore declines to adopt the commenter's suggestion.

*Comment:* A commenter suggested that the proposed rule is unnecessary since the E-2 program already supports international entrepreneurs.

*Response:* DHS disagrees with the commenter's statement. The E-2 program allows nationals of a treaty country (a country with which the United States maintains a qualifying Treaty of Friendship, Commerce and Navigation or its equivalent) to be admitted to the United States when investing a substantial amount of capital in a U.S. business. Foreign entrepreneurs from nontreaty countries, such as Brazil, China, India, Israel, or Russia, are currently not eligible for an E-2 nonimmigrant visa. Also, the E-2 category requires the entrepreneur to invest his or her own funds, and is therefore not applicable to entrepreneurs relying upon funds from investors or government entities to build and grow their business. DHS believes that this rule provides a viable option,

consistent with the Secretary's parole authority, to allow entrepreneurs to build and grow their businesses in the United States, providing significant public benefit here.

#### 4. Usefulness of the Rule

*Comment:* Multiple commenters argued that this rule will not necessarily help international entrepreneurs succeed, because there are too many restrictions in place for foreign residents to qualify. One commenter asserted that the rule as proposed is too complex and its goals will be impossible to achieve.

*Response:* DHS disagrees with these assertions. DHS acknowledges that this final rule will not benefit all international entrepreneurs seeking to enter or remain in the United States. As several commenters have stated, the final rule does not and cannot create a new visa classification specifically designed for international entrepreneurs, which is something that can only be done by Congress. This final rule, however, provides an additional option that may be available to those entrepreneurs who will provide a significant public benefit to the United States. This parole option complements, but does not supplant, current immigrant and nonimmigrant visa classifications for which some international entrepreneurs might qualify to bring or keep their start-up entities in the United States.

The requirements governing eligibility for consideration for parole under this rule establish a high evidentiary bar that must be met in order to assist DHS in its determination that the individual will provide a significant public benefit to the United States. DHS, however, does not agree with the commenter's assertion that the requirements are impossible for all entrepreneurs to meet. Given that this is a new and complex process, DHS will consider potential modifications in the future after assessing the implementation of the rule and its impact on operational resources.

#### 5. Include On-Campus Business Incubators in the Rule

*Comment:* One commenter urged USCIS to tie eligibility for parole to an applicant's participation in business incubators and accelerators located on U.S. university and college campuses that allow international entrepreneurs to grow start-up companies. The commenter stated that these programs meet the goal of the rule while providing benefits on a local and national scale. The commenter elaborated that the proposed rule only contemplates a traditional start-up arrangement, which creates

requirements based on ownership interest, type of investor, and amount of money invested. The commenter asserted that international entrepreneurs that engage with campus-based incubators cannot meet these requirements because the structure and opportunities provided by a higher education institution do not follow the traditional models. The commenter urged DHS to create alternative criteria to recognize the role higher education plays in fostering international entrepreneurs.

*Response:* DHS appreciates the comment but will not adopt changes to the rule in response. DHS recognizes and values the important role that incubators and accelerators located on a U.S. university or college campuses perform in the entrepreneur community. DHS believes, however, that the framework provided by this rule does allow DHS to consider, in its discretionary case-by-case determination, the fact that the start-up entity is participating in such an incubator or accelerator. DHS believes that evidence of such participation is one factor to be weighed for those individuals who do not fully meet the general capital investment or government funding criteria and are relying on additional reliable and compelling evidence that the start-up entity has the substantial potential for rapid growth and job creation. DHS believes that reliable and compelling evidence may, depending on all the circumstances, include evidence that the start-up entity is participating in a reputable incubator or accelerator located on a U.S. university or college campus.

#### 6. Objection to Use of the Word "Parole"

*Comment:* Multiple commenters objected to the use of the word "parole" to describe the provisions in this rule. Commenters are concerned that use of the word in an immigration context will be confused with the use of the word in the criminal context. A commentator suggested using the term "conditional status" or "provisional status."

*Response:* DHS declines to accept the commenters' suggestion. "Parole" is a term established by statute at section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5). The use of that term in the INA should not be confused with the word's usage in non-immigration contexts. Use of alternative terms as suggested by the commenter would be misleading.

<sup>35</sup> The E-2 nonimmigrant classification allows a national of a treaty country (a country with which the United States maintains a treaty of commerce and navigation) to be admitted to the United States when investing a substantial amount of his or her own capital in a U.S. business.

## 7. Concern Over Possible Exploitation of Entrepreneurs

*Comment:* Two commenters suggested that international entrepreneurs would be vulnerable to exploitation by venture capital investors under this rule. The commenters compare the influence of venture capitalists over entrepreneurs granted parole to the influence of employers over H-1B employees. One commenter expressed concern that the rule could allow a venture capitalist almost total dominance over the international entrepreneur's life, through the threat of withdrawing funding and thereby triggering termination of parole.

*Response:* DHS disagrees with the commenters' assertions that the final rule will facilitate such exploitation of international entrepreneurs by venture capital investors. As a general matter, venture capitalists and other investors cannot easily withdraw funding from a start-up entity once this investment transaction has been duly executed. Once an entrepreneur has applied for parole on the basis of prior investment, and has been granted such parole, the investor will not be in a position to directly interfere with the entrepreneur's continued eligibility during the parole period. The final rule will not create significant new conditions for exploitation that do not already exist currently for international entrepreneurs—or for that matter, domestic entrepreneurs—in the United States.

*Comment:* One commenter stated that the United States should be mindful of what may happen to poorer countries when the United States attracts their best entrepreneurs.

*Response:* DHS stresses that application for parole under this rule is voluntary and has the primary goal of yielding significant public benefit for the United States. DHS believes that applicants will assess economic and business conditions both in the United States and in other countries and will consider these conditions, along with numerous others, in the decision to apply for parole under this rule. DHS does not believe that the rule itself, which authorizes parole only for a limited period of time and under specific limited circumstances, will create significant negative consequences for poorer countries. Additionally, positive spillovers from new innovations are not limited to the specific country in which they were developed. Parole under this rule in no way prevents an entrepreneur contributing to the economy of his or her home, including through remittance

payments or upon return. Furthermore, individuals may be interested in returning to their home countries in the future for a variety of reasons, including the temporary nature of parole.

### M. Public Comments on Statutory and Regulatory Requirements

#### 1. Regulatory Impact Analysis

*Comment:* Two commenters suggested alternative estimates for the number of applicants that could apply to this rule. One commenter estimated that 5,000 international entrepreneurs will apply for parole under this rule. This estimate was approximately 2,000 more entrepreneurs than the estimate provided by DHS. Another commenter stated that the rule's eligibility criteria are narrow and therefore, the rule would cause fewer than 3,000 people to apply.

*Response:* DHS recognizes that uncertainty in business and economic conditions, as well as data limitations, make it difficult to accurately predict how many entrepreneurs will apply for parole under this rule. However, as discussed in the "Volume Projections" section of this rule, DHS utilized limited data available to estimate that approximately 2,940 entrepreneurs could seek parole each year. This estimate was bolstered by an alternative estimate based on accelerator investment round data that DHS analyzed. Given limits on DHS's information about such entrepreneurs and that this is a new process, DHS does not know how many people within the estimated eligible population will actually apply. Additionally, fluctuations in business and economic conditions could cause the number of applications to vary across years.

While one commenter estimates that the eligible number of entrepreneurs will be higher than the DHS estimate, another commenter estimates it will be lower. Neither of the commenters provided a basis or data from which their figures were derived. DHS reaffirms that the estimate provided in this rule is reasonable. The assessment is based on analysis of data and publicly available information, and reflects, where data and analysis allow, reasonable medians or averages.

*Comment:* One commenter argued that the rule would only benefit certain special-interest venture capitalists.

*Response:* DHS respectfully disagrees with this commenter. Fundamentally, this rule is designed to yield significant public benefit to the United States—including through economic growth, innovation, and job creation—and not to any particular private-sector interest group. While some venture capital firms may benefit from the rule by having new

opportunities to invest in start-up entities that would not have otherwise been able to locate in the United States, this is also true for a range of other "qualified investors" as defined in the rule. Moreover, many international entrepreneurs may qualify for parole under this rule without having raised private-sector capital investment at all, since funding from government entities is also an eligibility criterion.

*Comment:* Several commenters stated that the rule would provide significant economic benefits.

*Response:* DHS agrees with these commenters that the rule will provide significant economic benefits to the United States. As discussed in the proposed rule and elsewhere in this section, DHS believes that this rule will help the United States compete with programs implemented by other countries to attract international entrepreneurs. International entrepreneurs will continue to make outsized contributions to innovation and economic growth in the United States.

*Comment:* Several commenters provided feedback on the costs of applications. One commenter stated that the fees were reasonable. Another commenter suggested allowing market prices to determine parole costs, essentially allowing those entrepreneurs with more likelihood of success to invest in parole opportunities. Still other commenters stated that the application fee was too high, especially compared to various visa applications.

*Response:* DHS appreciates commenters' feedback on the costs for applications. DHS determines the costs of applications through a biennial fee study it conducts, which reviews USCIS' cost accounting process and adjusts fees to recover the full costs of services provided by USCIS. The established fees are necessary to fully recover costs and maintain adequate service by the agency, as required by INA section 286(m); 8 U.S.C. 1356(m).

*Comment:* Several commenters generally stated support for the rule because it will likely improve innovation for local and regional economic areas. Another commenter stated support for the rule because it would increase intangible assets.

*Response:* DHS concurs with this expectation that the rule will foster innovation at the local and regional level. Studies on entrepreneurs reveal that they are key drivers of innovation throughout the United States, and that such innovation benefits local, regional, and the national economy through technical progress and improvements in efficiency and productivity. The rule's

eligibility criteria focus on start-ups with high growth potential, and DHS expects that new firms started by entrepreneurs covered by the rule will conduct research and development, expand innovation, and bring new technologies and products to market in addition to creating jobs in the United States. These activities will produce benefits that will spill over to other firms and sectors.

DHS also agrees with the commenter on impacts to intangible assets. Intangible assets are generally integrated into a firm's or sector's total assets and have become important in broad analyses of productivity and efficiency. Such assets can include proprietary software, patents, and various forms of research and development. This rule is intended to attract the types of ventures that will increase intangible assets.

#### a. Job Creation

*Comment:* Many commenters agreed that this rule would help create jobs and significantly benefit the U.S. economy. A commenter noted that immigrants have helped to found one quarter of U.S. firms and therefore allowing more international entrepreneurs would result in new job creation. Commenters also mentioned that immigrants have historically been successful in creating and establishing new businesses, which in turn create jobs in the United States. Commenters also more specifically endorsed the need to provide more investment opportunities for venture capitalists and angel investors who indirectly create jobs. Finally, commenters from the technology industry stated that attracting entrepreneurs to the United States to operate in high unemployment areas could provide access to new jobs where they are most needed.

*Response:* DHS appreciates the commenters' support of this rule with regard to attracting international entrepreneurs, and emphasizes that job creation for U.S. workers is one of the rule's primary goals, as discussed in the Regulatory Impact Analysis (RIA).

#### b. Impact on Native U.S. Entrepreneurs and Native U.S. Workers

*Comment:* Several commenters suggested the rule will have negative consequences for native U.S. entrepreneurs and native U.S. workers. These commenters were concerned that the rule would be disadvantageous to native U.S. entrepreneurs and would create incentives for venture capital firms to find international entrepreneurs instead of investing in native U.S. entrepreneurs. The commenters argued that job creation could be accomplished

through investment of native U.S. entrepreneurs instead of foreign entrepreneurs. Several commenters also stated that the government should assist U.S. entrepreneurs and workers before helping international entrepreneurs. Commenters also mentioned that the need for international innovators was overstated and that the number of native U.S. innovators is already adequate. Finally, these commenters asserted that foreign workers are often exploited for cheap labor and harm job prospects for native U.S. workers.

*Response:* DHS disagrees with these commenters' assertion that the rule will have negative impacts on native U.S. entrepreneurs and native U.S. workers. This rule focuses on identifying entrepreneurs associated with start-up entities with significant potential for bringing growth, innovation, and job creation in the United States. Much research supports the conclusion that high-growth firms drive job creation for workers in the United States, including for native U.S. workers. As discussed in further detail in the RIA, research also shows that immigrants have been outsized contributors to business ownership and entrepreneurship in the United States and abroad. Self-employment rates for immigrants are higher than for the native U.S. population. As discussed in the RIA, although one economic study has suggested that a very small number of native U.S. entrepreneurs may be displaced by international entrepreneurs, other researchers have noted that the finding simply raises the possibility that such displacement could occur without providing evidence that it actually does.<sup>36</sup> DHS reiterates, moreover, that the numbers of entrepreneurs who may be eligible for parole under this rule is limited and that the aim of the rule is to increase overall entrepreneurial activity and significant economic benefit throughout the United States. In any event, the purpose of the parole rule is to foster innovation and entrepreneurial activities in new or very young endeavors, where the literature much more decisively indicates a strong potential of creating new net jobs for U.S. workers.

<sup>36</sup> Compare Fairlie, R.W., and B.D. Meyer. "The effect of immigration on native self-employment." *Journal of Labor Economics* 21:3 (2003): 619-650, available at: <http://people.ucsc.edu/~rfairlie/papers/published/jole%202003%20-%20native%20se.pdf>, with, e.g., Magnus Lofstrom, "Immigrants and Entrepreneurship," Public Policy Institute of California, USA, and IZA, Germany (2014), p. 4, available at: <http://wol.iza.org/articles/immigrants-and-entrepreneurship.pdf>.

#### c. Impact on Innovation

*Comment:* Several commenters provided feedback on the rule's impact on innovation. Two commenters stated that this type of international entrepreneurship supports innovation in the United States. Another commenter stated that the rule would not help foreign innovators because of complications with patents and modeling designs.

*Response:* DHS agrees with the commenters that stated that this rule supports innovation in the United States. Entrepreneurs tend to engage in research and development in order to develop and commercialize new products and technologies, and often stimulate patents and other intellectual capital linked to these efforts. DHS does not agree with the commenter that stated the rule is not helpful to foreign innovators because of issues with patents and modeling designs, and DHS sees no basis for this comment. Nothing in the rule poses specific burdens or constraints on the ability of entrepreneurs to seek and obtain patents or other intellectual capital.

#### 2. Review Under the National Environmental Policy Act (NEPA)

*Comment:* An advocacy organization stated that all rules, including immigration rules, are subject to review under the National Environmental Policy Act. The commenter suggested that, at minimum, an Environmental Assessment be conducted to account for the growth-inducing impacts that would occur with an influx in population under this rule.

*Response:* DHS agrees that NEPA applies to this, as to every, final rulemaking. As explained in section IV.E of this preamble, the rule has been reviewed for environmental effects and found to be within two categorical exclusions from further review because experience has shown rules of this nature have no significant impacts on the environment. DHS also notes that any entrepreneurial ventures undertaken will be governed by local, state and federal laws and regulations, including those protecting human health and the environment. We disagree with the commenter's assertion that an Environmental Assessment is required.

#### 3. Proposed Information Collections Under the Paperwork Reduction Act

##### a. Employment Eligibility Verification, Form I-9

*Comment:* An individual commenter suggested that List A documents should be updated to include the verified

driver's licenses (sample attached and included in the file) that meet federal guidelines and require the presentation of the same documentation needed to obtain a passport. The commenter stated that it is no longer reasonable for those who receive a verified license and who paid the premium necessary for the processing of the extra documents, to have to locate their birth certificate and social security card in order to complete the Form I-9 process.

*Response:* DHS presumes that by "verified driver's licenses" the commenter is referring to State driver's licenses that comply with the REAL ID Act of 2005, Public Law 109-13, 119 Stat. 302. The specific suggestion about amending List A on Form I-9, which would have wide-ranging effect and not be limited to entrepreneurs under this rule, is outside the scope of this rulemaking. This rule and accompanying form revisions limit changes to List A of Form I-9 to the modification of an existing document specified at 8 CFR 274a.2(b)(1)(v)(A)(5) to include individuals authorized to work incident to parole.

#### b. Application for Entrepreneur Parole, Form I-941

*Comment:* DHS received a public comment that stated that the time burden estimate of 1.33 hours for the respondent to complete the information collection was too low.

*Response:* DHS appreciates and agrees with this comment. Based on further review of the information collection and public comments on this specific issue, DHS is revising the estimated time burden from 1.33 hours to 4.7 hours for Form I-941 respondents.

#### 4. Comments and Responses to Impact on Small Businesses

*Comment:* The U.S. Small Business Administration, Office of Advocacy (SBA) commented by supporting the goals of this rule, but expressed concern that the rule could significantly impact small entities. The SBA commented that the proposed rule was erroneously certified under the Regulatory Flexibility Act (RFA). The SBA stated that the only international entrepreneurs eligible for this parole program are those with significant ownership stakes in a start-up entity formed in the previous three years. The SBA also stated that the thresholds to qualify for parole were directly tied to the ability of the entrepreneur's start-up to produce significant public benefit to the United States. The SBA noted that under the proposed rule, an entrepreneur is not permitted to transfer work authorization to another start-up

entity, and that these restrictions could impact start-up entities if the entrepreneur were no longer eligible to stay in the United States. For these reasons, SBA concluded that this rule directly impacts start-up entities. The SBA recommended that DHS submit a supplemental analysis on the impact of the final rule on small entities.

*Response:* DHS has concluded that a RFA certification statement for this final rule is appropriate. This final rule does not regulate small entities nor does it impose any mandatory requirements on such entities. Instead, it provides an option for certain individual entrepreneurs to seek parole on a voluntary basis. There are no compliance costs or direct costs for any entity, small or otherwise, imposed by this rule since it does not impose any mandatory requirements on any entity. Historically, when an employer petitions on behalf of an individual or employee, DHS has provided an RFA analysis for the impact to small businesses. However, under this rule, a small entity or an employer does not apply for parole on behalf of an employee; instead, an entrepreneur applies for parole on a voluntary basis on his or her own behalf, and only those eligible individuals seeking parole would be subject to the anticipated costs of application. Entrepreneurs with an ownership stake in a start-up make the cost-benefit decision to voluntarily apply for parole.

In both the RFA and SBA's Guide for Government Agencies on the RFA, government agencies are required to consider significant alternatives to the rule when providing a full RFA analysis. Among the kinds of alternatives that SBA suggests considering include "the exemption for certain or all small entities from coverage of the rule, in whole or in part."<sup>38</sup> Even if this rule directly impacted small entities and DHS were required to engage in an analysis to minimize negative impacts of the rule on small entities by exempting them from the rule, that alternative would only harm small entities, which would no longer be able to benefit from the rule's allowing entrepreneurs to seek parole and work authorization.

The SBA also commented on various policy issues on the eligibility of entrepreneurs in this rule. Notwithstanding DHS' belief that entrepreneurs when filing for parole are not small entities, DHS has carefully

considered all those comments and has made policy changes in this final rule to address the comments. Specifically, the SBA commented that thresholds to qualify for parole are directly tied to the ability of the international entrepreneur's start-up to produce significant public benefit for the United States. DHS has considered this comment along with other public comments on this issue and has made the decision to lower the eligible threshold investment amount for initial parole from the proposed \$345,000 in the NPRM to \$250,000 in the final rule. Additionally, in the NPRM and in this final rule, DHS has provided some flexibility and alternative criteria for those entrepreneurs meeting partial eligibility requirements, as described in further detail in the preamble.

SBA also commented that the rule only allows the entrepreneur to work for the business identified on the parole application without providing leniency in transferring the work authorization to another entity. The SBA further comments that the start-up entity may be imperiled if the entrepreneur is no longer eligible to stay in the United States. The eligibility criteria for consideration for parole under this rule require an entrepreneur to have recently formed a new entity in the United States with substantial potential for rapid growth and job creation. Before an application for parole under this rule is approved, USCIS must make a discretionary determination that the entrepreneur is well-positioned to provide a significant public benefit to the United States. Therefore, these eligibility criteria are not limiting entrepreneurs, but aimed at ensuring that only those entrepreneurs with high growth potential are eligible for parole consideration under this rule. DHS has also provided avenues for an additional parole period specifically to prevent instability of a start-up entity.

DHS reiterates that RFA guidance allows an agency to certify a rule, instead of preparing an analysis, if the rule is not expected to have a significant economic impact on a substantial number of small entities.<sup>39</sup> DHS reiterates that this rule does not regulate small entities. Any costs imposed on businesses will be driven by economic and business conditions and not by the

<sup>38</sup> The Regulatory Flexibility Act, 5 U.S.C. 603(c)(4). The Small Business Administration's RFA Guide for Government, p. 38, available at [https://www.sba.gov/sites/default/files/advocacy/rfaguide\\_0512\\_0.pdf](https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf).

<sup>39</sup> See SBA, Office of Advocacy, "A Guide for Government Agencies; "How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272" (May 2012), available at: [https://www.sba.gov/sites/default/files/advocacy/rfaguide\\_0512\\_0.pdf](https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf).

voluntary participation for benefits from this rule.

#### IV. Statutory and Regulatory Requirements

##### A. *Unfunded Mandates Reform Act of 1995*

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The value equivalent of \$100 million in 1995 adjusted for inflation to 2015 levels by the Consumer Price Index for All Urban Consumers (CPI-U) is \$155 million.

This rule does not exceed the \$100 million expenditure in any one year when adjusted for inflation (\$155 million in 2015 dollars), and this rulemaking does not contain such a mandate. The requirements of Title II of the Act, therefore, do not apply, and DHS has not prepared a statement under the Act.

##### B. *Small Business Regulatory Enforcement Fairness Act of 1996*

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

##### C. *Executive Orders 12866 and 13563*

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” under section 3(f) of

Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

##### 1. Summary

This final rule is intended to add new regulatory provisions guiding the use of parole with respect to individual international entrepreneurs who operate start-up entities and who can demonstrate through evidence of substantial and demonstrated potential for rapid business growth and job creation that they would provide a significant public benefit to the United States. Such potential is indicated by, among other things, the receipt of significant capital financing from U.S. investors with established records of successful investments, or obtaining significant awards or grants from certain Federal, State or local government entities. The regulatory amendments will provide the general criteria for considering requests for parole submitted by such entrepreneurs.

DHS assesses that this final rule will, by further implementing authority provided by Congress, reduce a barrier to entry for new innovative research and entrepreneurial activity in the U.S. economy.<sup>40</sup> Under this final rule, some additional international entrepreneurs will be able to pursue their entrepreneurial endeavors in the United States and contribute to the U.S. economy. In the absence of the rule, these innovative entrepreneurs might be delayed or discouraged altogether in bringing innovation, job creation, and other benefits to the United States.

Based on review of data on startup entities, foreign ownership trends, and Federal research grants, DHS expects that approximately 2,940 entrepreneurs, arising from 2,105 new firms with investment capital and about 835 new firms with Federal research grants, could be eligible for this parole program annually. This estimate assumes that each new firm is started by one person despite the possibility of up to three owners being associated with each start-up. DHS has not estimated the potential for increased demand for parole among foreign nationals who may obtain

<sup>40</sup>Nina Roberts, *For foreign tech entrepreneurs, getting a visa to work in the US is a struggle*, The Guardian, Sept. 14, 2014, available at <http://www.theguardian.com/business/2014/sep/14/foreign-tech-entrepreneurs-visa-us-struggle>; Amy Grenier, *Majority of U.S. Patents Granted to Foreign Individuals*, April 11, 2014, available at <http://immigrationimpact.com/2014/04/11/majority-of-u-s-patents-granted-to-foreign-individuals/> (“Because of the limitations of the H-1B visa program, and the lack of a dedicated immigrant visa for entrepreneurs or innovators, foreign inventors struggle with inadequate visa options that often prevent them from obtaining permanent residency.”).

substantial investment from U.S. investors and otherwise qualify for entrepreneur parole, because changes in the global market for entrepreneurs, or other exogenous factors, could affect the eligible population. Therefore, these volume projections should be interpreted as a reasonable estimate of the eligible population based on past conditions extrapolated forward. Eligible foreign nationals who choose to apply for parole as an entrepreneur will incur the following costs: A filing fee for the Application for Entrepreneur Parole (Form I-941) in the amount of \$1,200 to cover the processing costs for the application; a fee of \$85 for biometrics submission; and the opportunity costs of time associated with completing the application and biometrics collection. After monetizing the expected opportunity costs and combining them with the filing fees, an eligible foreign national applying for parole as an entrepreneur will face a total cost of \$1,591. Any subsequent renewals of the parole period will result in the same previously discussed costs. Filings to notify USCIS of material changes to the basis for the entrepreneur’s parole, when required, will result in similar costs; specifically, in certain instances the entrepreneur will be required to submit to USCIS a new Form I-941 application to notify USCIS of such material changes and will thus bear the direct filing cost and concomitant opportunity cost. However, because the \$85 biometrics fee will not be required with such filings, these costs will be slightly lower than those associated with the initial parole request and any request for re-parole.

Dependent spouses and children who seek parole to accompany or join the principal applicant by filing an Application for Travel Document (Form I-131), will be required to submit biographical information and biometrics as well. Based on a principal applicant population of 2,940 entrepreneurs, DHS assumes a total of 3,234 spouses and children will be eligible for parole under this rule. Each dependent will incur a filing fee of \$575, a biometric processing fee of \$85 (if 14 years of age and over) and the opportunity costs associated with completing the Form I-131 application and biometrics collection.<sup>41</sup> After monetizing the expected opportunity costs associated with providing biographical information to USCIS and submitting biometrics and combining it with the biometrics

<sup>41</sup>The filing fees have been updated and reflect those promulgated in the 2016 Fee Rule (1615-AC09, CIS No. 2577-15 DHS Docket No. USCIS-2016-0001).

processing fee, each dependent applicant will face a total cost of \$765. DHS is also allowing the spouse of an entrepreneur paroled under this rule to apply for work authorization. Using a one-to-one mapping of principal filers to spouses, the total population of spouses eligible to apply for work authorization is 2,940. To obtain work authorization, the entrepreneur's spouse will be required to file an Application for Employment Authorization (Form I-765), incurring a \$410 filing fee and the opportunity costs of time associated with completing the application. After monetizing the expected opportunity costs and combining it with the filing fees, an eligible spouse will face a total additional cost of \$446 (rounded). DHS expects that applicants will face the above costs, but does not anticipate that this rule will generate significant additional costs and burdens to private entities, or that the rule will generate additional processing costs to the government to process applications. While applicants may face a number of costs linked to their business or research endeavors, these costs will be driven by the business and innovative activity that the entrepreneur is engaged in and many other exogenous factors, not the rule itself or any processes related to the rule. Thorough review of academic, business, and policy research does not indicate that significant expected costs or negative consequences linked to attracting international entrepreneurs are likely to occur. As such, DHS expects that the negative consequences, if any, will be greatly exceeded by the positive effects of this rule.

In each case in which an entrepreneur will be granted parole under this rule, DHS will have made a determination that parole will yield a significant public benefit and that the person requesting parole merits a favorable exercise of discretion. Consistent with those decisions, the rule is expected to produce broad economic benefits through the creation of new business ventures that otherwise would not be formed in the United States. These businesses are likely to create significant additional innovation, productivity, and job creation. It is reasonable to conclude that investment and research spending on new firms associated with this rule will directly and indirectly benefit the U.S. economy and create jobs for American workers. In addition, innovation and research and development spending are likely to generate new patents and new technologies, further enhancing innovation. Some portion of the international entrepreneurs likely to be

attracted to this parole process may develop high-growth and high-impact firms that can be expected to contribute disproportionately to U.S. job creation. In summary, DHS anticipates that this rule will produce positive effects that would greatly exceed any negative consequences.

Using an estimate of 2,940 annual applications for significant public benefit entrepreneur parole as developed in the ensuing volume projections section of this analysis, DHS anticipates the total cost of this rule for principal filers who face a total per applicant cost of \$1,591 to be \$4,678,336 (undiscounted) annually for any given year. (These estimates focus only on principal initial filers, not entrepreneurs who might be eligible for a re-parole period of up to 30 months, or their spouses.) Dependent spouses and children who must submit the Form I-131 application and biometrics will face a per-applicant cost of \$765, for a total cost of \$2,474,914 (undiscounted). Dependent spouses who apply for employment authorization will face a per applicant cost of \$446, which DHS projects will total \$1,311,830 (undiscounted). Adding together the costs for the principal filers and family members—including filing costs, costs of submitting biometrics, and monetized opportunity costs—yields a total cost of this rule for the first year, 2017 and subsequently 2018, of \$8,465,080 (undiscounted). The total annual cost of the rule of \$8,465,080 can be expected for each subsequent year in the ten-year period. The total ten-year undiscounted cost is \$84,650,081.

## 2. Background and Purpose of the Rule

Section 212(d)(5) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(5), grants the Secretary of Homeland Security the discretionary authority to parole applicants for admission into the United States temporarily, on a case-by-case basis, for urgent humanitarian reasons or significant public benefit. DHS is amending its regulations implementing this authority to increase and enhance entrepreneurship, research and development and other forms of innovation, and job creation in the United States. The rule will establish general criteria for the use of parole with respect to individual entrepreneurs who operate start-up entities and who can demonstrate through evidence of substantial and demonstrated potential for rapid business growth and job creation that they would provide a significant public benefit to the United States.

The purpose of the rule is to attract talented entrepreneurs to the United States who might otherwise choose to pursue such innovative activities abroad, or otherwise be significantly delayed in growing their companies in the United States, given the barriers they presently face. In addition to the benefits associated with entrepreneurial innovation, including new products, business networks, and production efficiencies that such activities are likely to generate, entrepreneurs have been and remain vital to economic growth and job creation in the United States and have generated a cohort of high-growth firms that have driven a highly disproportionate share of net new job creation.<sup>42</sup>

A body of research documents both the importance of entrepreneurial activity to the U.S. economy and its link to immigration. In this background section, DHS does not attempt to comprehensively summarize this large body of work but instead focuses on specific aspects central to the purpose of the rule and to its potential impacts.<sup>43</sup> In summary, DHS focuses on the role of new entrepreneurial firms in job creation in the United States, and the role that immigrant entrepreneurs have played in innovation and the high technology sector.

The labor market of the United States is highly dynamic. DHS analysis of data published by the U.S. Department of Labor's Bureau of Labor Statistics (BLS) indicates that between 2004 and 2013, on average about 847,000 firms were "born" each year and 784,000 "died."<sup>44</sup> To illustrate the extent of the labor market churn, since 1980 the private sector has generated about 16.3 million gross jobs annually but an average of only about 1.4 million net jobs annually. In both general business cycle expansions and contractions, large numbers of jobs are created and destroyed, comprising a key dynamic in the forces of creative destruction.<sup>45</sup>

<sup>42</sup> See Richard L. Clayton, Akbar Sadeghi, David M. Talan, and James R. Spletzer, *High-employment-growth firms: Defining and counting them*, Office of Industry Employment Statistics, Bureau of Labor Statistics (BLS), Monthly Labor Review (June 2013), p. 1-2, available at: <http://www.bls.gov/opub/mlr/2013/article/pdf/clayton.pdf>.

<sup>43</sup> DHS notes that the body of research concerning immigration in general and its impact on the labor market, most notably germane to earnings and employment of domestic workers, is not addressed in the present analysis.

<sup>44</sup> Figures were obtained from the BLS, Business employment Dynamics, Table 8, "Private sector establishment births and deaths, seasonally adjusted," available at <http://www.bls.gov/news.release/cewbd.t08.htm>. Firm "births" in these data only include new firms and thus exclude new franchises and expansions of existing firms.

<sup>45</sup> See Ryan Decker, John Haltiwanger, Ron Jarmin, and Javier Miranda, *The Role of*

Research into the highly dynamic and volatile labor market in the United States has evolved. Earlier focuses on small- and new-firm size as the primary co-determinants of job creation has been reoriented to focus on the role of a relatively small subset of entrepreneurial firms.

This rule focuses on identifying entrepreneurs associated with types of start-up firms that are more likely to experience high growth, contribute to innovation, and create jobs in the United States. This deliberate focus is critical to ensuring that parole in individual cases is justified by significant public benefit. Research has shown that the average start-up company does not survive long.<sup>46</sup> Most new firms do not add much net job creation either, as they are not focused on achieving high growth. By some estimates, the vast majority—as much as 95 percent—of all new firms are not substantial job creators or innovators.<sup>47</sup> About 95 percent of new firms start with fewer than 20 employees, and about the same percentage ultimately close with fewer than 20 employees, indicating that business turnover is heavily influenced by small firms.<sup>48</sup>

There is significant research, however, demonstrating that a small subset of new firms tends to be highly dynamic and to contribute disproportionately to net job creation. The BLS has highlighted the role of the small subset of high-growth firms that comprise about 2 percent of all firms but have accounted for 35 percent of gross job gains in recent years. “High-growth

firms” are defined by the BLS and the Organization for Economic Cooperation (OECD) as those with at least ten employees that grow by at least 20 percent for each of 3 consecutive years based on employment. As of 2012, there were 96,900 high-growth firms in the United States that had created about 4.2 million jobs.<sup>49</sup> A key finding by the BLS is that high-growth firms especially add jobs in their first ten years, though they generally continue to add a diminishing number of new jobs even after that period of time to the extent they survive. Job creation in the United States for the last several decades has been driven primarily by high-growth firms that tend to be young and new, and by a smaller number of surviving high-growth firms that age for a decade or more.<sup>50</sup>

This highly disproportionate, “up or out” dynamism of high-growth firms has been substantiated by many researchers. The SBA reported that about 350,000 “high impact firms”—defined as enterprises whose sales have at least doubled over a 4-year period and which have an employment growth quantifier of 2 or more over the same period—generated almost all net new jobs in the United States between 1994 and 2006.<sup>51</sup> The Kauffman Foundation, a leading institute on research, data collection, and advocacy for entrepreneurial activity, reports that the top-performing one percent of firms generates roughly 40 percent of new job creation, and, the fastest of them all—the “gazelles”—comprising less than one percent of all companies, generated roughly ten percent of new jobs.<sup>52</sup> The

same general result has been found internationally; the OECD reports that between three percent and six percent of all firms can be considered high-growth firms but about one percent can be considered the even more high-performing “gazelles.”<sup>53</sup>

Despite the finding across a large number of studies that small new firms tend to exhibit an “up or out” dynamic in which a small number survive to age five to become high-growth firms or “gazelles,” other key findings that have emerged in the literature suggest that the growth and performance of new firms, even high-growth firms, vary substantially (as indicated by metrics that include labor productivity, profitability, revenue, and research and development intensity).<sup>54</sup> Models that can sort out various business characteristics and economic conditions to predict high-growth probabilities are still in nascent stages. Nevertheless, this rule includes threshold criteria for parole consideration meant to identify entrepreneurs associated with the kinds of promising start-up entities that appear more likely to contribute to American innovation, economic development, and job creation. As described in more detail below, businesses started and run by immigrants have propelled these kinds of broadly shared economic benefits for many years.

Broadly speaking, high-growth entrepreneurs engage in research and development (R&D) in order to develop and commercialize new products and technologies. Several studies have found that such entrepreneurs tend to engage in R&D spending in the first year, tend to attract patents and other forms of intellectual capital, and tend to attract venture capital financing.<sup>55</sup>

*research%20reports%20and%20covers/2010/04/highgrowthfirmsstudy.pdf.*

<sup>53</sup> David B. Audretsch, *Determinants of High-Growth Entrepreneurship*, report prepared for the OECD/DBA International Workshop on High-growth firms: local policies and local determinants, OECD, p. 2–5, available at: [http://www.oecd.org/cfe/leed/Audretsch\\_determinants%20of%20high-growth%20firms.pdf](http://www.oecd.org/cfe/leed/Audretsch_determinants%20of%20high-growth%20firms.pdf).

<sup>54</sup> See R. Decker et al (2014), *supra* n. 53, pp. 5–7; see also Davis, Steven J., R. Jason Faberman, John Haltiwanger, Ron Jarmin, and Javier Miranda, *Business Volatility, Job Destruction, and Unemployment*. American Economic Journal: Macroeconomics 2(2) (2010): 259–87. Research and development intensity is typically measured as the ratio of research and development spending to revenue, net income, or overall costs.

<sup>55</sup> See Shah, Sonali K. and Winston Smith, Sheryl and Reedy, E. J., *Who are User Entrepreneurs? Findings on Innovation, Founder Characteristics, and Firm Characteristics*, The Kauffman Firm Survey (Feb. 2012), pp. 2–5, available at: [http://www.kauffman.org/~media/kauffman\\_org/research%20reports%20and%20covers/2012/02/whoareuserentrepreneurs.pdf](http://www.kauffman.org/~media/kauffman_org/research%20reports%20and%20covers/2012/02/whoareuserentrepreneurs.pdf).

*Entrepreneurship in U.S. Job Creation and Economic Dynamism*, Journal of Economic Perspectives—Vol. 28, Number 3 (Summer 2014), pp. 3–24, available at: <http://pubs.aeaweb.org/doi/pdfplus/10.1257/jep.28.3.3>.

<sup>46</sup> According to BLS findings, “20 percent of newly created establishments don’t survive their first year in business, 32 percent don’t survive their first two years, and 50 percent don’t survive their first 5 years.” See Richard L. Clayton, Akbar Sadeghi, David M. Talan, and James R. Spletzer, *High-employment-growth firms: Defining and counting them*, Office of Industry Employment Statistics, Bureau of Labor Statistics (BLS), Monthly Labor Review (June 2013), p. 1, available at: <http://www.bls.gov/opub/mlr/2013/article/pdf/clayton.pdf>.

<sup>47</sup> See Jason Wiens and Chris Jackson, *The Importance of Young Firms for Economic Growth*, Ewing Marion Kauffman Foundation (2014), pp. 1–2, available at: [http://www.kauffman.org/~media/kauffman\\_org/resources/2014/entrepreneurship%20policy%20digest/september%202014/entrepreneurship\\_policy\\_digest\\_september2014.pdf](http://www.kauffman.org/~media/kauffman_org/resources/2014/entrepreneurship%20policy%20digest/september%202014/entrepreneurship_policy_digest_september2014.pdf); see also Hurst, Erik, and Benjamin Wild Pugsley. 2011; *What Do Small Businesses Do?* Brookings Paper on Economic Activity, no. 2 (2011), pp. 73–142.

<sup>48</sup> See Headd, Brian, *An Analysis of Small Business and Jobs*, SBA Office of Advocacy (2010), p. 6, available at: [https://www.sba.gov/sites/default/files/files/an%20analysis%20of%20small%20business%20and%20jobs\(1\).pdf](https://www.sba.gov/sites/default/files/files/an%20analysis%20of%20small%20business%20and%20jobs(1).pdf).

<sup>49</sup> See R. Clayton et al. (June 2013), *supra* n. 50, p. 2–4. For a description of the methodology utilized to measure high growth firms, see OECD, *OECD-Eurostat Manual on Business Demography Statistics* (2007), pp. 59–65, available at: <http://www.oecd.org/std/39974460.pdf>.

<sup>50</sup> For specific detailed information on survival rates and employment creation at various intervals along the HGF life span, see R. Decker et al. (2014), *supra* n. 53, pp. 6–24. The BLS and others use the term “gazelles” to differentiate the fastest growing young HGFs.

<sup>51</sup> See Spencer Tracy, Jr., *Accelerating Job Creation in America: The Promise of High-Impact Companies*, SBA Office of Advocacy (2011), pp. 1–4, available at: <https://www.sba.gov/sites/default/files/advocacy/HighImpactReport.pdf>; see also Acs, Zoltan, William Parsons, and Spencer L. Tracy, Jr., *High-Impact Firms: Gazelles Revisited*; Study prepared for the SBA, Office of Advocacy (2008), p. 1, available at: <http://www.sba.gov/advocacy/research/irs328tot.pdf>. The SBA high-impact cohort is about 6.3% of all firms, which is higher than the 2% high-growth category found in the BLS studies. The SBA cohort is larger because the criteria are slightly less restrictive and it includes older firms.

<sup>52</sup> See Dane Stangler, *High-Growth Firms and the Future of the American Economy*, Kauffman Foundation Research Series: Firm Formation and Economic Growth (2010), p. 2, available at: [http://www.kauffman.org/~media/kauffman\\_org/](http://www.kauffman.org/~media/kauffman_org/)



Immigrants have been central contributors to business ownership and entrepreneurship in the United States and abroad. According to OECD data, self-employment rates for immigrants are higher than those of the native-born populations in many countries, including in the United States.<sup>56</sup> Based on the most recent data available from the U.S. Census Bureau, 12.9 percent of the United States population was foreign-born. Their rate of self-employment is about 30 percent higher than that of the native-born population (7.7 percent vs. 5.9 percent; n=1.8 million). The Census Bureau's 2012 Survey of Business Owners showed that 14.4 percent of U.S. firms were owned by at least one person not born a citizen of the United States.<sup>57</sup> Two studies based on samples of U.S. firms found slightly higher foreign-born ownership rates.<sup>58</sup>

Many high-growth firms are involved in activities classified in the STEM (science, technology, engineering, and math) fields. The high concentration of immigrant entrepreneurs in these industries has garnered much attention. Between 2006 and 2012, one-third of companies financed with venture capital that made an initial public offering had an immigrant founder, a sharp rise from seven percent in 1980. These companies have generated 66,000 jobs and \$17 billion in sales.<sup>59</sup> A survey

<sup>56</sup> OECD, *Migrant Entrepreneurship in OECD Countries*, prepared by Maria Vincenza Desiderio (OECD) and Josep Mestres-Domènech for the Working Party on Migration (2011), pp. 141–144, available at: [http://www.oecd.org/els/mig/Part%20II\\_Entrepreneurs\\_engl.pdf](http://www.oecd.org/els/mig/Part%20II_Entrepreneurs_engl.pdf). This, and many other similar studies and analyses are based on self-employment rates, which are a proxy, but not a perfect measure, of business ownership, because some ownership structures such as partnerships, that could involve a foreign-born owner, are generally not considered to be proprietary.

<sup>57</sup> The categorization of “foreign-born” does not differentiate between lawful permanent residents and naturalized citizens. It also does not provide details of the firm history, implying that some firms owned by persons not born in the United States could have been founded by U.S. citizens and sold to foreign-born persons.

<sup>58</sup> See David M. Hart, Zoltan J. Acs, and Spencer L. Tracy, Jr., *High-tech Immigrant Entrepreneurship in the United States*; report developed under a contract with the Small Business Administration, Office of Advocacy (2009), page 8, available at: [https://www.sba.gov/sites/default/files/advocacy/rs349tot\\_0.pdf](https://www.sba.gov/sites/default/files/advocacy/rs349tot_0.pdf); see also Robert W. Fairlie and Magnus Lofstrom, *Immigration and Entrepreneurship*, Institute for the Study of Labor (2013), p. 1, available at: <http://ftp.iza.org/dp7669.pdf>. The foreign born ownership rates for U.S. firms reported in these papers is 16% and 18.2%, in order.

<sup>59</sup> This information is found from various sources and found in Stuart Anderson, *American Made 2.0. How Immigrant Entrepreneurs Continue to Contribute to the United States Economy*, National Foundation for American Policy, sponsored by the National Venture Capital Association (NVCA) (2013), pp. 3–7.

of entrepreneurs in technology-oriented privately held companies with venture backing also showed about one-third were foreign born, and 61 percent held at least one patent.<sup>60</sup>

Further evidence points to similar findings. Between 1995 and 2005, 25 percent of science and technology focused businesses founded in the United States had a foreign-born chief executive or lead technologist. In 2005, those companies generated \$52 billion in sales revenue and employed 450,000 workers. In Silicon Valley, the share of immigrant-founded start-ups increased to 52 percent by 2005. In 2006, foreign nationals residing in the United States were involved (as inventors or co-inventors) in about 26 percent of patent applications filed that year. Immigrant founders of Silicon Valley firms tend to be highly educated, with 96 percent holding bachelor's degrees and 74 percent holding advanced degrees, and with three-quarters of the latter in STEM fields. As of 2010, according to one study, more than 40 percent of the Fortune 500 companies had been founded by an immigrant or the child of an immigrant.<sup>61</sup>

To reiterate, high-growth firms tend to be new and young, and one of their primary contributions to the highly dynamic labor market of the United States has been through job creation. High-growth firms tend to innovate and focus on developing new products and services. The intense involvement of immigrant entrepreneurs in successful technology-driven activities suggests substantial economic contributions. While measuring the precise value and impact of innovation is difficult and still at a nascent stage in research, many economists believe innovation creates positive externalities and spillover effects that further drive economic growth.<sup>62</sup>

Notwithstanding the research on the positive effects of high-growth entrepreneurship, there is some evidence of a long-term slowing in start-up dynamism and entrepreneurial activity in the United States; this trend began several decades ago, driving many economists to advocate for policies that attract more entrepreneurs in general.<sup>63</sup> Many business entrepreneurial

<sup>60</sup> *Id.* at pp. 2–5.

<sup>61</sup> Vivek Wadhwa, *Foreign-Born Entrepreneurs: An Underestimated American Resource*, Ewing Marion Kauffman Foundation (2008), pp. 2–6, available at: [http://www.kauffman.org/-/media/kauffman\\_org/z\\_archive/article/2008/11/wadhwatbook09.pdf](http://www.kauffman.org/-/media/kauffman_org/z_archive/article/2008/11/wadhwatbook09.pdf).

<sup>62</sup> See SMEs, *Entrepreneurship and Innovation*, OECD (2010), pp 26–28, available at: <http://www.oecd.org/berlin/45493007.pdf>.

<sup>63</sup> See R. Decker et al. (2014), *supra* n. 53, p. 16–22.

advocacy centers have also advocated in recent years for the United States to enact a formalized pathway for immigrant entrepreneurs. DHS is aware of one estimate of the potential benefits of a theoretical start-up visa (which, as an entirely new visa classification, only Congress can create). A Kauffman Foundation study (2013) estimated that, under certain conditions, the establishment of a start-up visa program could lead to the creation of between 500,000 and 1.6 million new jobs after ten years.<sup>64</sup> The potential benefits of attracting immigrant entrepreneurs have not gone unnoticed internationally. Thirteen of the thirty-five nations that are part of the Organization of Economic Cooperation and Development (OECD) have enacted special immigration programs for entrepreneurs, although the eligibility criteria vary among them to a significant extent.<sup>65</sup>

### 3. Population of Entrepreneurs Potentially Eligible

DHS cannot precisely predict the volume of new businesses that will start in the United States due to this rule. DHS has instead examined available data to provide a broad estimate of the population of individual entrepreneurs who may be eligible to request parole consideration under this rule. Given limits on DHS's information about such entrepreneurs, DHS does not know how many people within the estimated eligible population will actually seek such consideration; the estimates contained in this section represent an approximation to the size of the eligible population. DHS has estimated the population of entrepreneurs potentially eligible for parole under this rule based on two sub-groups: (1) Foreign individuals who seek to come to the United States to start a new business with financial backing from a qualified U.S. investor; and (2) foreign individuals who seek to come to the United States to start a new business as recipients of U.S. funded and awarded

<sup>64</sup> See Dane Stangler and Jared Konczal, *Give Me your Entrepreneurs, Your Innovators; Estimating the Employment Impact of a Startup Visa*, Ewing Marion Kauffman Foundation, (Feb. 2013), pp. 1–3, available at: [http://www.kauffman.org/-/media/kauffman\\_org/research%20reports%20and%20covers/2013/02/startup\\_visa\\_impact\\_finalsada](http://www.kauffman.org/-/media/kauffman_org/research%20reports%20and%20covers/2013/02/startup_visa_impact_finalsada). The estimates are based on a fixed pool of 75,000 startup visas for a 10-year period, in which firm deaths each year cycle some of visa to new entrants.

<sup>65</sup> Most programs have been enacted after 2010. A country list and some descriptive data can be found at Jean-Christophe Dumont, *Investor Visas in OECD Countries*, OECD Conference on Global High-Skilled Immigration Policy, The National Academies Board on Science, Technology and Economic Policy (2014), available at: [http://sites.nationalacademies.org/cs/groups/pgasite/documents/Web\\_page/pgasite\\_152202.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/Web_page/pgasite_152202.pdf).

research grants and who intend to conduct the concomitant research in the United States. DHS assumes that each member of the eligible population will start a business and that the general criterion for investment from a qualified investor (*e.g.*, venture capital firms, angel investors, or accelerators or incubators) be set at \$250,000, while for government grants or awards the general criterion will be \$100,000. Based on these amounts, DHS analyzed various past endeavors for the potential sources of funds. DHS estimates that approximately 2,940 foreign nationals annually could be eligible to apply for parole under this rule. Table 1 summarizes the analysis by source of funds.

TABLE 1—NUMBER OF ENTREPRENEURS POTENTIALLY ELIGIBLE

Sub-group	Annual eligibility
New firms funded with investment capital .....	2,105
New firms funded with U.S. grants or awards .....	835
Total .....	2,940

DHS has no way of predicting with certainty the actual number of foreign nationals who will seek parole under this rule over time, as the size of the eligible population could change significantly. DHS acknowledges that the estimate of eligible individuals annually is an approximation based on past foreign ownership and start-up capital amounts. The analysis utilized to estimate the potential eligible population is also based implicitly on assumptions that: (1) The rule will not significantly change the frequency of U.S. funded grant applications from international researchers; and (2) that the rule will not significantly affect the market for international entrepreneurs and the market for the types of investment structures the rule will involve. Based on these assumptions and the data limitations, DHS projects that for the first full year that the rule will be effective, annual eligibility will be approximately 2,940.<sup>66</sup> DHS projects

<sup>66</sup> DHS emphasizes that the total is a broad estimate, as the Department has no means to determine the demand for entrepreneurial parole, changes in the eligible population that the rule may cause, time-variant possibilities, and application preferences. These conditions could change, if, for example, some foreign researchers see parole as attractive and apply for federally funded grants that they otherwise might not have applied for in the absence of the rule. In addition, volume estimates should be interpreted to apply to only initial applications, not considerations for re-parole at some future point in time. Lastly, the market for the

that this number will hold steady for the second year as well. The next section provides key data and analytical approaches utilized to arrive at the estimates of eligible individuals. DHS first considers volume estimates of eligible individuals based on official U.S. data. The resulting estimates based on official data are those utilized for the cost projections of the rule. Due to particular constraints in the data, DHS follows with an alternative method of volume estimation of eligible individuals that adds robustness to the official estimate.

#### Volume Projections Data and Methodology

##### A. Grants

Because U.S.-funded research grants may be a qualifying investment under this rule, DHS obtained publicly available data on federally funded grants for fiscal years 2013–2015.<sup>67</sup> Although numerous agencies within the Federal Government award grants to foreign-born individuals, most are humanitarian or development focused.<sup>68</sup> For this reason DHS parsed the very large data set comprising 1.7 million records to obtain a viable analytical cohort. First, the records were filtered to capture Federal Government agencies that award grants to both United States and foreign-born recipients. Secondly, the records were sorted to only include the Federal Government agencies that award grants focused on “projects,” thereby excluding block and assistance grants.<sup>69</sup> The foreign-born cohort used for the eligibility projections excluded grants made to recipients in U.S. territories, as such recipients may be subject to special considerations outside the

types of investments involved, such as venture capital, are fluid and becoming more global in scope. DHS has no means to determine how the evolution of these investment markets will affect, or be affected by, the rule.

<sup>67</sup> The data were obtained from USASpending.gov: <https://www.usaspending.gov/Pages/Default.aspx>. From the homepage, the data can be accessed from the linked “data download” section. The files were obtained on April 20, 2015.

<sup>68</sup> It is certainly the case that U.S. State governments and other governmental entities issue research grants that foreign recipients could potentially utilize for parole eligibility. However, DHS is not aware of any database that collects and provides such data publicly.

<sup>69</sup> The Federal entities that awarded scientific focused research to foreign recipients were: Agricultural Resource Service, National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, Department of Defense, National Aeronautics and Space Administration, National Oceanic and Atmospheric Administration, National Institute of Standards and Technology, and National Science Foundation. The U.S. Department of State and the Agency for International Development (USAID) were excluded from the analysis.

parole parameters.<sup>70</sup> DHS also excluded grant amounts recorded as negative, zero, and trivial amounts of less than \$1,000—such values were recorded if grants were rescinded or for some other reason not ultimately funded. On average, 138,447 grants comprised the annual resulting analytical cohort derived from the above filtering procedures. Of that total, a small portion, 2,043 grants, or 1.5 percent, were awarded to foreign-born individuals. Having determined a reasonable eligibility threshold of \$100,000, DHS proceeded to the next step, to determine the potential annual eligible population of grant-sourced researchers. Over the period of analysis, 41 percent of the Federal grants awarded to foreign recipients equaled or surpassed the \$100,000 benchmark, for an average of 835 annually.

##### B. Investment Capital

To estimate the number of potential new entrepreneurial start-ups, DHS obtained and analyzed data from the BLS and the Census Bureau. From the BLS Business Employment Dynamics (BED) data suite, DHS obtained the number of private establishments aged 1 year or less for nine broad sectors likely to be involved in innovative activity, in order to focus on entrants.<sup>71</sup> Although a reasonable proxy, the number of establishments aged 1 year or less is not a perfect measure of firm start-ups (births). The chosen metric may

<sup>70</sup> There is a particular way in which the data germane to foreign grants were parsed and analyzed. There are two possible foreign indicators listed for each grant. One is the “principal place” involving the research and the other is the “recipient country.” The incumbent volume projections are based on the latter because this indicator generally implies that the grant was made to a person or institution outside the United States. The former is not used because this indicator could apply to grants awarded to U.S. or foreign persons in order to conduct the ensuing research outside the United States. Implicit in this analysis is that persons awarded U.S.-funded grants that are overseas could conduct their research and innovation in the United States, and are not otherwise precluded from doing so, even if the focus of such research is in a foreign country.

<sup>71</sup> The BLS data is found at <http://www.bls.gov/bdm/bdmage.htm>. DHS utilized the “Establishment age and survival BED data for nation by major industry” set and figures from Table 5, “Number of private sector establishments by age,” for the nine major sectors shown in Table 2. The BLS does provide figures on firm births that could be used in the present analysis. However, DHS chose establishment age data because it is broken down in a way that corresponds precisely to the innovating sectors, discussed below. The firm birth data is not categorized in the exact same manner. The nine major sectors were chosen to envelope the approximately 430 individual activities that DHS considers to involve “science, technology, engineering, and math” (STEM). The full list based on the 2012 update can be found at <http://www.ice.gov/sites/default/files/documents/Document/2014/stem-list.pdf>.

overstate births, by including expansions and new franchises of existing businesses. Conversely, it may understate the actual number of start-ups, because some fraction of firms does not survive the first year (the data are tabulated in March of the respective year such that the establishments aged 1 year and less are those that opened within the previous year but remained in business as of March of the following year), and those that opened in the previous year and were still in business but had not reached 2 years of age. DHS utilized the relevant figure for March 2015, because the latter is the most recent figure reported in the BED dataset.

For each sector, DHS obtained the corresponding share of firms owned by a person “not born a citizen of the United States” from the Census Bureau’s Survey of Business Owners

data set.<sup>72-73</sup> For brevity, we utilize the term “foreign” here to describe such firms. The foreign share was obtained by dividing the number of foreign-owned private firms in a sector by the total number of reporting firms in the same sector. This share applies to firms that have a least one owner who was not born in the United States but does not differentiate between various types of ownership structures. The figure for new firms obtained from the BLS BED data was multiplied first by the foreign share to generate an estimate of firms per sector started by a person not born in the United States.

Next, DHS attempted to calculate how many of the firms were started with at least \$250,000, the minimum investment threshold that the rule sets. The SBO data provides ranges of such startup capital amounts but DHS could not conduct a precise estimate because

the data do not provide a category bound by the threshold minimum. In fact, the encompassing tranche is very large, from \$249,500 to \$1 million in range. The SBO does not provide actual cohort data or other information from which DHS could evaluate the distribution and, therefore, DHS has no way of ascertaining how many firms in this large range will occupy the \$250,000 to \$1 million segment. As a result, DHS relied on the share of firms in this tranche and the additional tranches over \$1,000,000 relative to the share of all firms reporting for the sector, and recognizes that the volume projection is likely larger than is realistic. An additional assumption is that the startup threshold is the same for businesses with native and foreign-born founders. The relevant data and estimates per sector are shown in Table 2.

TABLE 2—SUMMARY OF ENTREPRENEUR ESTIMATES

Sector	New firms	Foreign share (%)	Start-up threshold (%)	Annual eligible
Agriculture .....	10,182	4.9	2.5	12
Utilities .....	1,204	10.8	5.5	7
Manufacturing .....	29,883	11.0	5.4	178
Information .....	22,855	11.9	2.0	55
Professional Services* .....	165,425	12.8	1.2	248
Management .....	7,334	7.3	20.2	108
Waste Services .....	66,161	16.4	0.9	94
Education .....	15,226	11.9	0.7	13
Health Care .....	210,977	18.0	3.7	1,391
Total .....				2,105

\* Abbreviation for “Professional, Scientific, and Technical Services”.

As is discussed in the preamble, DHS has revised two substantive components of the eligibility criteria for this final rule. Foremost, the general investment amount requirement has been lowered from \$345,000 to \$250,000. DHS believes that the volume estimate of entrepreneurs based on investment capital will be higher than the 2,105 presented above but cannot make a determination of exactly how much higher. The reason is that the lower investment amount will allow some firms to be created that otherwise would not at the higher amount proposed initially, but the Census Bureau capital

size bin relevant to the level proposed is the \$249,500 to \$1 million in range, which includes both figures. Because DHS does not have data on the distribution of amounts within this range, the entire bin was included in the proposed estimates and is retained in the final estimates. However, as is described below, DHS has conducted an alternative method of estimation—to include updates from the initial proposal based on new information and data—that compares very closely to the estimated total volume of 2,940. Specifically, an alternative estimate of total volume annually is 2,920.

C. An Alternative Estimate of Entrepreneurs Based on Investment Structures

DHS recognizes the imperfections in estimating the potential population of eligible entrepreneurs based on extrapolating past conditions of foreign ownership rates and capital thresholds. The main benefit of this method is that it is based on official data. A main limitation is that it assumes that the annual crop of firms created are entrepreneurial and the types of firms covered by the parole process in the rule. In practice, some, but not all, will

<sup>72</sup> The Census SBO data are found at: <http://www.census.gov/data/tables/2012/econ/sbo/2012-sbo-characteristics.html>. The foreign ownership figures per sector are found under “Characteristics of Business owners,” Table SB1200CSBO11: “Statistics for Owners of Respondent Firms by Whether the Owner Was Born in the United States by Gender, Ethnicity, Race, and Veteran Status for the U.S.” and the startup capital data are found under Characteristics of Businesses, Table SB1200CSB16: “Statistics for All United States

Firms by Total Amount of Capital Used to Start or Acquire the Business by Industry, Gender, Ethnicity, Race, and Veteran Status for the United States: 2007.” The foreign ownership share of firms is provided in the table and thus did not need to be calculated by DHS. The SBO data are part of the 2012 survey for which data was released publicly between February and June 2016.

<sup>73</sup> A possible source of upward bias in the foreign ownership share and hence the estimate of eligible entrepreneurs is that this share does not

differentiate between foreign owners who came to the United States to open a business and those who acquired one after being in the United States for some period of time (e.g., lawful permanent residents or naturalized citizens). A general finding among the literature on this topic is that many foreign-born business owners were driven to start a business by “push” factors in the labor market after arrival in the United States. DHS does not have a means to parse out the ownership rate in a more granular way to account for such differences.

be innovators, even though the present analysis focuses on the sectors of the economy linked to STEM activity (DHS is not aware of any methods or data that can allocate a research-innovation share of firms to each sector). A second limitation is that the DHS method of measuring new firms in the context of the rule is imprecise. The final rule revised the definition of “start-up entity” in 8 CFR 212.19(a)(2) to include firms that were formed up to 5 years prior to the filing of the application for parole, compared to three years as proposed in the NPRM. However, the BLS cohort of new firms utilized for the volume projections are 1 year of age or less, not five or even three years, and is thus a smaller estimate of the number of new firms that could be eligible. This limitation cannot be overcome because of the manner in which the survival cohorts are presented.<sup>74</sup> Because the volume projections are derived from information obtained from official sources—the BLS and Census Bureau—DHS retains them for purposes of the costs and volume estimates of the rule. DHS believes, however, that an alternative method of estimation will inform readers and strengthen the regulatory analysis by providing a viable comparison to the official projections. In this alternative approach, DHS focuses on business accelerators and incubators (described together as “accelerators” for brevity). By analyzing the foreign component of these structures, data permitting, an alternative estimate of entrepreneurs can be obtained for comparison purposes.

DHS obtained publicly available information from Seed-DB, which provides data on U.S. accelerators collected from industry associations and fee-based data providers such as Crunchbase, which is a large data provider for venture capital, angel

investors, and accelerators.<sup>75</sup> From the Seed-DB Web site DHS utilized the link to “firms that have exited” to collect the cohort of firms that underwent accelerators and then exited via an acquisition or public offering. Next, DHS parsed the data to capture firms that reported total funding, exit value, and were not recorded as “dead” (last accessed on Nov. 7, 2016). The parsing described above yielded a cohort of 89 firms. DHS followed the Seed-DB links to Crunchbase for each firm and extracted the seed round, recording its value.<sup>76</sup> Analysis of the investment rounds reveals that the median is \$250,000. Having determined a median seed round size from the data, DHS next attempted to estimate a foreign share of accelerated firms. The exit cohort from which the median was calculated did not provide such information, hence DHS turned to the Seed-DB data suite that lists the total number of companies incubated for each accelerator and the countries that the companies were located in. Since there is wide variation in the number of companies per incubator, ranging from 1 to over a thousand, DHS grouped the incubators by country and then weighted each one for its share of total companies. The resulting weighted average indicates that one quarter of incubated companies were foreign.<sup>77</sup> Having determined a median seed round and a foreign share estimate, the final point required is the number of firms to apply these figures to. Based on the most recent data from the Center for Venture Research, the 2013–2015 annual average for angel financed firms in the seed and startup phase was 33 percent, which equals 23,336 firms annually. Multiplying this

average number of firms by 0.25 to capture the foreign share and then by 0.5 to reflect the median and also the investment level DHS has set yields an annual estimate of 2,920.

This estimate compares well to the official total volume estimate of 2,940. The accelerator data captures seed rounds that involve venture capital, angel, accelerator investments, and grants, which is why it is compared to the total volume estimate.

#### D. Potential Variability in the Volume Projections

This section discusses several potential cohorts involving entrepreneurial activity that is difficult to estimate.

In light of the potential benefits to the U.S. economy and job creation, DHS is proposing this rule to provide a mechanism that, consistent with the requirements of the INA, encourages international entrepreneurs described herein to form and create innovative firms in the United States. In 2011, DHS began outreach and stood up the Entrepreneurs in Residence initiative to try to encourage entrepreneurship among foreign nationals.<sup>78</sup> DHS began tracking the number of foreign nationals who indicated interest in starting up an entrepreneurial endeavor at some point during their admission as an H-1B nonimmigrant. Over four fiscal years (FY 2010–2013), an average of 77 foreign nationals indicated such interest. In light of the relatively small numbers of foreign nationals who indicated their entrepreneurial intentions, DHS believes that considering parole requests under this rule will promote further innovation and other economic benefits in addition to those created by existing programs and policies used by foreign nationals to pursue high-growth entrepreneurial activity in the United States. When the rule is effective, there could be some small substitution effects as some portion of this cohort could switch to seeking parole instead of relying on other existing nonimmigrant programs and policies. DHS, however, does not believe such substitution will occur on a large scale because the ability to be admitted to the United States as a nonimmigrant offers materially more benefits and protections than parole.

In addition, the rule lists a number of ancillary conditions for eligibility—and conversely a number of conditions that

<sup>75</sup> The Seed-DB information is found at [www.seed-db.com/](http://www.seed-db.com/).

<sup>76</sup> For most of the firms in the exit cohort, the initial round of investment date-wise was also the smallest round in terms of value and labeled as the “seed” or “angel” round. For about 10 percent of the firms however, determining which round to use for the analysis was not straightforward and DHS had to utilize some discretion. For example, for some firms the seed round was listed after other rounds, such as venture capital or Series A rounds. For others, the seed round was not the smallest round recorded. DHS does not know why these anomalies are present but proceeded to choose the “seed round” regardless of its dating or amount. The only exception was in the few cases in which the seed round post-dated other rounds and was larger in amount. In these few cases the initial round was chosen, regardless of what investment type it was.

<sup>77</sup> This foreign share found by DHS in the analysis corresponds strongly to a finding in a study of high technology firms that found that 24 percent of such firms were founded by a foreign born person. See *America's New Immigrant Entrepreneurs*, Vivek Wadhwa, AnnaLee Saxenian, Ben Rissing, and Gary Gereffi, available at: [http://people.ischool.berkeley.edu/~anno/Papers/Americas\\_new\\_immigrant\\_entrepreneurs\\_1.pdf](http://people.ischool.berkeley.edu/~anno/Papers/Americas_new_immigrant_entrepreneurs_1.pdf).

<sup>74</sup> Specifically, the BLS BED provides the number of firms surviving to a specific age and below. For example, the five year cohort includes all firms started within five years surviving up to that point, and so on for younger cohorts. However, the data does not count the number of firms within each survival cohort by their true age. Hence, the five year survivals do not include firms that started up and may have died after three years that could have been eligible at one time. Therefore, the five year survival cohort significantly undercounts the number of firms that will potentially have been considered new in the context of the final rule. Conversely, adding up the survival cohorts to a point, say year five, will significantly over-count the number of firms considered new in the context of the final rule. The reason is that a firm that survived four years and went on to age five will be included in both the five and four year cohort, not to mention the younger ones. Thus, adding the two (age four and five) cohorts together would double count the survivor. This problem is less onerous for firms aged one or zero.

<sup>78</sup> Source: “USCIS Announces ‘Entrepreneurs in Residence Initiative,’” available at: <http://www.uscis.gov/news/public-releases-topic/business-immigration/uscis-announces-entrepreneurs-residence-initiative>; see also <http://www.uscis.gov/eir/visa-guide/entrepreneur-visa-guide>.

will leave individuals unlikely or unable to be paroled into the United States (or continue to be paroled in the country). Because ancillary conditions can be considered for eligibility, the actual volume may be smaller than the estimates herein. Two examples are that, under the rule, applicants must maintain household income greater than 400 percent of the poverty line and that the qualifying start-up capital cannot come from family members. The volume estimates presented in this analysis assume all ancillary eligibility conditions are met.

Finally, two potential elements of the eligible population are considered. First, as alluded to in the summary, the volume estimates and ensuing cost estimates assume one individual owner for each new firm; under the rule, DHS will allow up to three individuals per firm to seek parole but does not attempt to estimate how many of the startups could have more than one owner. Second, the volume estimate for grants is based on Federal awards only. DHS will consider eligibility based on State or local grants and awards, including those from State or local Economic Development Corporations (EDCs). However, unlike in the case of Federal awards, there is not a database capturing State and local grants or the transmission mechanisms through which some Federal grants are distributed to other entities, such as EDCs, and as such DHS was unable to estimate the number of entrepreneurs potentially eligible for parole as a result of receiving State and local grants.

#### 4. Costs

##### A. Principal Filer Costs

The rule will permit certain foreign nationals to apply for a 30-month (2.5-year) initial period of parole into the United States provided they meet the eligibility criteria. Those who seek such parole into the United States will face the costs associated with the application, which involve a \$1,200 application fee plus other costs, detailed below. The costs will stem from filing fees and the opportunity costs of time associated with filing the Application for Entrepreneur Parole (Form I-941).

The filing fee for the Form I-941 application is \$1,200. The fee is set at a level intended to recover the anticipated processing costs to DHS.<sup>79</sup>

<sup>79</sup> USCIS calculates its fees to recover the full cost of USCIS operations, including meeting national security, customer service, and adjudicative processing goals. As with other fees, USCIS uses Activity Based Costing (ABC) to assign costs to specific benefit requests. This model uses completion rates (actual or estimated depending on whether the benefit type is already being

In addition, DHS is proposing that applicants for parole as an entrepreneur submit biometrics and incur the \$85 biometric services fee. Because entrepreneurs could start firms in any number of occupations, DHS believes it is appropriate to utilize the mean hourly wage for all occupations, which is \$22.71.<sup>80</sup> In order to anticipate the full opportunity cost to petitioners, DHS multiplied the average hourly U.S. wage rate by 1.46 to account for the full cost of employee benefits such as paid leave, insurance, and retirement, for a total of \$33.16 per hour.

DHS estimates that the application will take 4.7 hours to complete. After DHS receives the application and fees, if the applicant is physically present in the United States, USCIS will send the applicant a notice scheduling him or her to visit a USCIS Application Support Center (ASC) for biometrics collection. Along with the \$85 biometric services fee, the applicant will incur the following costs to comply with the biometrics submission requirement: the opportunity cost of traveling to an ASC, the mileage cost of traveling to an ASC, and the opportunity cost of time for submitting his or her biometrics. While travel times and distances vary, DHS estimates that an applicant's average roundtrip distance to an ASC is 50 miles, and that the average time for that trip is 2.5 hours. DHS estimates that an applicant waits an average of 1.17 hours for service and to have his or her biometrics collected at an ASC, adding up to a total biometrics-related time burden of 3.67 hours.<sup>81</sup> By applying the

adjudicated) to calculate a fee or fee adjustment for a benefit type. A completion rate reflects an average time an adjudicator spends actually working on a case but does not include "queue" or wait times. Because parole under this rule has not yet been implemented, the completion rate used is based on a 4-hour estimate provided by USCIS' subject matter experts. At this time, USCIS has estimated that 30 additional staff will be required to satisfy the forecasted workload associated with this rule. However, USCIS requires adjudicators to report actual adjudication hours and case completions by benefit type. This reporting will occur after this rule is implemented. Adjudication hours will be divided by the number of completions for the same time period to determine the *actual* average completion rate. This rate will be used in future fee adjustments and will help determine future staffing allocations necessary to handle the projected workload for parole under this rule.

<sup>80</sup> Please see U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics program, National Occupational Employment and Wage Estimates, United States (May 2014), available at: [http://www.bls.gov/oes/2014/may/oes\\_nat.htm](http://www.bls.gov/oes/2014/may/oes_nat.htm).

<sup>81</sup> Foreign nationals who submit their applications from outside the United States will still be required to pay the \$85 biometric processing fee and travel to a USCIS office abroad, if available, or a U.S. embassy or consulate office for biometric processing at the time of travel document issuance. Due to data limitations, and to capture general

\$33.16 hourly time value for applicants to the total biometrics-related time burden, DHS finds that the opportunity cost for a principal applicant to travel to and from an ASC, and to submit biometrics, will total \$121.68.<sup>82</sup> In addition to the opportunity cost of providing biometrics, applicants will experience travel costs related to biometrics collection. The cost of such travel will equal \$28.75 per trip, based on the 50-mile roundtrip distance to an ASC and the General Services Administration's (GSA) travel rate of \$0.575 per mile.<sup>83</sup> DHS assumes that each individual will travel independently to an ASC to submit his or her biometrics, meaning that this rule will impose a time cost on each of these applicants.

DHS estimates that each principal parole applicant will incur the following costs: \$1,285 in filing fees to cover the processing costs for the application and biometrics; \$306.27 after summing the monetized cost of travel to submit biometrics, the total opportunity costs of time of the initial applications, biometrics, and estimated travel costs, resulting in a total cost of \$1,591.27 per application, rounded to \$1,591.<sup>84</sup> If DHS receives 2,940 applications from persons eligible to apply, DHS anticipates that such applications will result in annual filing fee transfers of \$3,777,900 (undiscounted), which comprise the application fee and cost of submitting biometrics, and opportunity and other burden costs of \$900,436 for a total annual cost of \$4,678,366. Any subsequent renewal of the parole period will result in costs similar to those previously discussed, with the exceptions of travel costs, since the applicant will not be required to depart the United States and re-enter. Similarly, the same costs will result for material changes requiring the filing of amended applications, with the exception of the travel costs noted above and costs associated with biometrics collections, including the time and travel to an ASC.

impacts of the rule, DHS has estimated costs of submitting biometrics under the assumption that all applicants are traveling to an ASC in the United States.

<sup>82</sup> Calculation: \$33.16 \* 3.67 hours = \$121.68.

<sup>83</sup> Calculation: 50 miles multiplied by \$0.575 per mile equals \$28.75. See 79 FR 78437 (Dec. 30, 2014) for GSA mileage rate.

<sup>84</sup> Calculation: \$1,285 + 306; \$1,285 is the sum of the direct cost of the \$1,200 filing fee and the \$85 cost of biometrics. The \$306 (rounded) figure is obtained by adding the cost of travel (\$28.75) plus the total opportunity cost of \$277, the latter of which is the product of the total time burden (8.37 hours) and the average burdened hourly wage (\$33.16).

## B. Dependent Spouses and Children

The rule will require all dependent family members (spouses and children) accompanying or joining the entrepreneur to file an Application for Travel Document (Form I-131), and will require all spouses and children 14 years of age through age 79 to submit biometrics.<sup>85</sup> Those spouses and children will face the costs associated with filing the application and submitting biometrics. DHS recognizes that many dependent spouses and children do not currently participate in the U.S. labor market, and as a result, are not represented in national average wage calculations. In order to provide a reasonable proxy of time valuation, DHS has to assume some value of time above zero and therefore uses an hourly cost burdened minimum wage rate of \$10.59 to estimate the opportunity cost of time for dependent spouses. The value of \$10.59 per hour represents the Federal minimum wage with an upward adjustment for benefits.<sup>86</sup> The value of \$10.59 per hour is consistent with other DHS rulemakings when estimating time burden costs for those who are not authorized to work.<sup>87</sup>

DHS will require dependents of parole applicants (spouses and children of the parole applicant) to file an Application for Travel Document (Form I-131). There is a \$575 filing fee associated with the Form I-131 application, and DHS estimates it will take 3.56 hours to complete each submission. In addition to filing the Form I-131 application, each dependent spouse and child 14 years of age and over will be required to submit biometric information (fingerprints, photograph, and signature) by attending a biometrics services appointment at a designated USCIS Application Support Center (ASC). The biometrics processing fee is \$85.00 per applicant. In addition to the \$85 biometrics services fee, the applicant will incur the following costs to comply with the biometrics submission requirement: the opportunity and mileage costs of

traveling to an ASC, and the opportunity cost of submitting his or her biometrics. While travel times and distances vary, DHS estimates that an applicant's average roundtrip distance to an ASC is 50 miles, and that the average time for that trip is 2.5 hours.<sup>88</sup> DHS estimates that an applicant waits an average of 1.17 hours for service and to have his or her biometrics collected at an ASC, adding up to a total biometrics-related time burden of 3.67 hours. In addition to the opportunity cost of providing biometrics, applicants will experience travel costs related to biometrics collection. The cost of such travel will equal \$28.75 per trip, based on the 50-mile roundtrip distance to an ASC and the General Services Administration's (GSA) travel rate of \$0.575 per mile.<sup>89</sup> DHS has assumed that each applicant will travel independently to an ASC to submit his or her biometrics, meaning that this rule will impose a time cost on each of these applicants. DHS also assumed all children were over the age of 14 for the purposes of this analysis and, therefore, this cost estimate may be slightly overestimated.

DHS projects that approximately 3,234 dependents will be required to file a Form I-131 application and submit biometrics, based on the estimate of 2,940 principal applicants and using a multiplier for expected family members of 1.1.<sup>90</sup> The total cost for those spouses and children requesting parole under this program includes the filing fee, biometrics processing fee, travel costs associated with biometrics processing, and the opportunity cost of filing the Form I-131 application and submitting

<sup>88</sup> DHS has estimated travel distances and ensuing travel times at 2.5 hours in prior rulemakings. See, e.g., "Employment Authorization for Certain H-4 Dependent Spouses; Final rule," 80 FR 10284 (Feb. 25, 2015); and "Provisional and Unlawful Presence Waivers of Inadmissibility for Certain Immediate Relatives; Final Rule," 78 FR 536, 572 (Jan. 3, 2013).

<sup>89</sup> See U.S. General Services Administration Web site for Privately Owned Vehicle (POV) Mileage Reimbursement Rates, <http://www.gsa.gov/portal/content/100715> (accessed Aug. 8, 2015).

<sup>90</sup> The multiplier of 1.1 was obtained from DHS estimates of the average historical ratio of principal versus dependent recipients of lawful permanent resident status. DHS studies based on statistics obtained from office of Immigration Statistics reveal that multipliers for the employment preference categories EB-1, EB-2, and EB-3 range from 2.04 to 2.27. DHS believes that 2.1 is a reasonable multiplier for the estimates and utilized this multiplier in regulatory assessments involved in American Competitiveness in the Twenty-First Century Act, (AC21) provisions, specifically: "Retention of EB-1, EB-2, and EB-3 Immigrant Workers and Program Improvements Affecting High-Skilled Nonimmigrant Workers" (RIN 1615-AC05), rule. Because the Form I-131 filings relevant to this rule do not apply to principals, only spouses and dependent children, DHS believes it is valid to subtract 1 from the 2.1 multiplier to yield the final multiplier of 1.1.

biometrics. The total time burden is 7.23 hours. At the cost-burdened wage, the total opportunity cost is \$76.53. Adding the \$28.75 cost of travel, the total non-filing cost is estimated to be \$105.28, and the total cost per applicant is \$765.28. At the projection of 3,234 applicants, the non-filing cost is \$340,474 (undiscounted), and combined with filing costs of \$2,134,440, the total estimated cost for dependents germane to the Form I-131 application is \$2,474,914.

In addition, DHS is allowing independent employment authorization for spouses of entrepreneurs granted parole under this rule. DHS will permit these individuals to apply for employment authorization by filing a Form I-765 application. To estimate the number of potential persons applying for employment authorization, DHS used a simple one-to-one mapping of entrepreneurs to spouses to obtain 2,940 spouses, the same number as entrepreneur parolees.

The current filing fee for the Form I-765 application is \$410.00. The fee is set at a level to recover the processing costs to DHS. Based on the projection of 2,940 applicants, the total filing cost is \$1,205,400 (undiscounted). DHS estimates the time burden of completing the Form I-765 application is 3.42 hours.<sup>91</sup> At the cost-burdened wage, the total opportunity cost is \$36.20. At the projection of 2,940 applicants, the non-filing cost is \$106,430 (undiscounted) and combined with filing costs of \$1,205,400 the total estimated cost for spouses germane to the Form I-765 application is \$1,311,830.

In addition to the filing costs, applicants for parole may face other costs associated with their entrepreneurial activities. These could include the administrative costs of starting up a business, applying for grants, obtaining various types of licenses and permits, and pursuing qualified investments. However, these costs apply to the entrepreneurial activity and the business activity that the applicant has chosen to be involved in and are not driven by the parole process or other governmental functions attributable to the rule itself. Hence, DHS does not attempt to estimate, quantify, or monetize such costs.

Lastly, DHS recognizes that some individuals who were lawfully admitted in the United States in certain nonimmigrant classifications may seek

<sup>91</sup> Source: Paperwork Reduction Act (PRA) Supporting Statement for Form I-765 (OMB control number 1615-0040). The PRA Supporting Statement can be found at Question 13 on [Reginfo.gov](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201502-1615-004) at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201502-1615-004](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201502-1615-004).

<sup>85</sup> Note: If a child under the age of 14 requires a travel document, he or she will need to appear for biometrics by traveling to an ASC, but will not be required to pay a biometrics fee.

<sup>86</sup> U.S. Department of Labor, Wage and Hour Division. The minimum wage in effect as of July 24, 2009. Available at <http://www.dol.gov/dol/topic/wages/minimumwage.htm>. The calculation for total employer costs for employee compensation for dependent spouses and children of principals with an approved Form I-140: \$7.25 per hour × 1.46 = \$10.59 per hour.

<sup>87</sup> See "Employment Authorization for Certain H-4 Dependent Spouses; Final rule," 80 FR 10284 (Feb. 25, 2015); and "Provisional and Unlawful Presence Waivers of Inadmissibility for Certain Immediate Relatives; Final Rule," 78 FR 536, 572 (Jan. 3, 2013).

parole. Individuals who are present in the United States at the time their parole application is approved, based on admission as a nonimmigrant, will have to depart the United States and appear at a U.S. port of entry in order to be granted parole since USCIS is unable to grant parole to individuals who are not applicants for admission. See INA section 212(d)(5), 8 U.S.C. 1182(d)(5). These individuals will be ineligible for a change of status under section 248 of the INA, 8 U.S.C. 1258. Such applicants will therefore bear the travel costs of exit and returning to a port of entry. However, because there are no similar programs for comparison, DHS cannot determine the demand for parole or substitution effects from other classifications and thus cannot estimate, quantify, or monetize such potential travel costs. Finally, because the program allows for re-parole under conditions that DHS has set, entrepreneurs and their spouse and children, if applicable, will likely face filing and opportunity costs associated with applying for re-parole. However, DHS has no means of estimating the share of the potential eligible population that will seek and be eligible for re-parole, hence re-parole conditions are not included in this analysis. In summary, DHS believes that it is possible that there could be some substitution into the parole program from other programs and such applicants and dependents will incur travel and possible other costs related to exit and requesting a grant of parole at a U.S. port of entry.

#### C. Potential for Negative U.S. Labor Market Impacts

DHS does not expect the rule to generate significant costs or negative consequences. Extensive review of information relevant to immigrant entrepreneurship indicates that while much about the impact of such entrepreneurship is not known, there is no reason to expect that substantial negative consequences, including adverse impact on domestic workers, are likely. The possibility that immigrant entrepreneurs may displace (“crowd-out”) native entrepreneurs has been raised by a few researchers. One study indicated that a very small number of native entrepreneurs were possibly displaced by immigrant entrepreneurs.<sup>92</sup> However, because of difficulties in controlling for a large amount of variables related to

<sup>92</sup> Fairlie, R.W., and B.D. Meyer, *The effect of immigration on native self-employment*, Journal of Labor Economics 21:3 (2003): 619–650, available at <http://people.ucsc.edu/~rfairlie/papers/published/jole%202003%20-%20native%20se.pdf>.

entrepreneurship, other researchers have noted that this finding only raises the possibility that displacement could not be ruled out completely, but did not actually provide evidence that it had actually occurred.<sup>93</sup> Another study, conducted by the Brookings Institution, did not find displacement but acknowledged that more research and refined control techniques, along with longitudinal data, will need to be studied before ruling out the possibility completely.<sup>94</sup> In any event, the purpose of the parole rule is to foster innovation and entrepreneurial activities in new or very young endeavors, where the literature much more decisively indicates a strong potential of creating new net jobs for U.S. workers.

DHS recognizes that the potential inclusion of spouses can incur labor market implications and possibly impact U.S. workers. As was noted in previous sections of the regulatory impact analysis, DHS did not attempt to assess or measure the labor market impact of the estimated entrepreneurs potentially eligible for parole because as founders of firms, these persons will not affect the labor market in the same way as other workers. Although spouses could have labor market impacts as new labor market entrants, DHS believes such potential impacts will be negligible. The main reason is that the size of the potential new cohort is very small. As of the end of 2015, there were an estimated 157,130,000 people in the U.S. civilian labor force.<sup>95</sup> Consequently, the estimated “new” available workers in the first year will represent approximately 0.001 percent of the overall U.S. civilian labor force.<sup>96</sup> DHS believes this fraction is too small

<sup>93</sup> See Magnus Lofstrom, *Immigrants and Entrepreneurship*, Public Policy Institute of California, USA, and IZA, Germany (2014), p. 4, available at: <http://wol.iza.org/articles/immigrants-and-entrepreneurship.pdf>.

<sup>94</sup> See Zoltan J. Acs and David M. Hart, *Immigration and High-Impact, High-Tech Entrepreneurship*, Brookings, Issues in Technological Innovation (Feb. 2011), available at <http://www.brookings.edu/research/papers/2011/02/immigration-hart-ac>.

<sup>95</sup> See News Release, United States Department of Labor, Bureau of Labor Statistics, Local Area Unemployment Statistics, Regional and State Unemployment—2015 Annual Averages, Table 1 “Employment status of the civilian non-institutional population 16 years of age and over by region, division, and state, 2014–15 annual averages” (Mar. 24, 2016), available at <http://www.bls.gov/news.release/pdf/srgune.pdf>.

<sup>96</sup> Source: United States Department of Labor, Bureau of Labor Statistics, Local Area Unemployment Statistic. Figure applies to seasonally adjusted level for December 2014, available at <http://data.bls.gov/timeseries/LNS11000000>. Calculation for new worker labor force share:  $1813/157,130,000$ .

to have a significant impact on the labor market.

While the figures above apply to the general U.S. labor force, DHS recognizes that concentration of new labor force entrants can impact specific labor markets. DHS believes that any such potential impacts linked to this rule will be insignificant. The NVCA and other sources of information that DHS reviewed indicates that while the area of California known as Silicon Valley has traditionally been, and continues to be, the primary recipient geographically for technology startup capital, other large urban centers on the East Coast and, even more recently, parts of the Mid- and Mountain West have seen increased technology startup activity. To provide just one example of a potential area-specific impact, DHS considered the San Jose-San Francisco-Oakland (CA) Combined Statistical Area (CSA) conjoining the seven Metropolitan Statistical Areas (MSAs) and nine encompassed counties constituting the economic linkages of Silicon Valley. Based on data from the BLS, the population of this CSA is about 8.6 million (as of May 2014) and the employed population (a narrower measure of the labor market than the labor force) about 3.75 million. If the share of new entrants is based on the proportion of venture capital to the area, which is 42 percent, then 2,746 spousal entrants could impact the area.<sup>97</sup> Assuming such entrants gain employment, this cohort represents just 0.02 percent of the employed population of the specific CSA.

#### D. Government Costs

The INA provides for the collection of fees at a level that will ensure recovery of the full costs of providing services, including administrative costs and services provided without charge to certain applicants and petitioners. See INA section 286(m), 8 U.S.C. 1356(m). DHS has established the fee for the adjudication of the Form I-941 application based on notional application filing volumes and estimated resource commitments. During the biennial fee review, DHS

<sup>97</sup> The employment figures are provided by the BLS, Occupational Employment Statistics (OES), found at: [http://www.bls.gov/oes/current/oes\\_42100.htm](http://www.bls.gov/oes/current/oes_42100.htm). The population data is provided by the Census Bureau, which tabulates CSAs: “Combined Statistical Area Totals Dataset: Population and Estimated Components of Change: April 1, 2010 to July 1, 2014” (CSV), 2014 Population Estimates. United States Census Bureau, Population Division. March 2015. The information on the venture capital share for the region is found in the NVCA 2015 yearbook, and is found in figure 8, p. 14. The calculation is as follows:  $(.42 \times 1813) = 761$ , which is then divided by the CSA population of 3,750,000.



will examine whether the fee is sufficient to recover the full costs of adjudication, as required by the INA.

#### 5. Benefits

As referenced previously, evidence suggests that innovation-focused start-ups contribute disproportionately to job creation. The rule will reduce entry barriers, and thus support efforts by international entrepreneurs to generate entrepreneurial activity in the United States.

The rule is expected to generate important net benefits to the U.S. economy. For one, expenditures on research and development by the grant-based researchers that DHS has identified that could qualify for entrepreneur parole will generate direct and indirect jobs. In addition, this research-focused spending could potentially generate patents, intellectual property, licensing, and other intangible assets that can be expected to contribute to innovation and technological advances and spill over into other sectors of the overall economy. DHS acknowledges that it is extremely difficult to gauge the precise economic value of such assets and that peer-reviewed research in this area is still nascent. Despite the nascent stage of the research and the difficulty of measuring quantitatively the benefit of innovation driven by new high technology firms, a large body of research indicates that the innovation driven by entrepreneurs contributes directly to economic growth, generates important efficiencies and cost reductions for firms that utilize such innovation, and increases productivity and profitability for firms that benefit indirectly through new products generated by such innovation.

Lastly, DHS believes that many of the start-up firms operated by international entrepreneurs during the parole period could eventually become high-growth firms that generate exceptionally high levels of economic activity and contribute disproportionately to job creation in the United States.

#### D. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601(6), DHS examined the impact of this rule on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act, 15 U.S.C. 632), a small not-for-profit organization, or a small governmental jurisdiction (locality with fewer than 50,000 people).

In the proposed rule, DHS certified that this rule would not have a

significant impact on a substantial number of small entities. DHS made this determination based on the following facts: This is not a mandatory rule; this rule only impacts those individual entrepreneurs who make the voluntary decision to apply for parole; and this rule does not regulate the business entities in any way. After reviewing public comments, including the formal letter submitted on the record by the U.S. Small Business Administration's Office of Advocacy (Advocacy), DHS maintains its certification that the rule does impose a significant impact on a substantial number of small entities. For a full discussion of the DHS response to the letter submitted by Advocacy, please see Section III.M.4 of this preamble.

Individuals are not defined as a "small entity" by the RFA. The rule will not mandate that all individuals apply for parole. This rule provides flexibilities and options that do not currently exist for individuals who wish to establish or operate a start-up business in the United States. Importantly, the rule does not require any individuals or businesses, including those created by foreign nationals, to seek parole—either generally or as a specific condition for establishing or operating a business in the United States. Rather, as mentioned previously, this rule is intended to provide an additional flexibility for foreign individuals who are unable to obtain another appropriate nonimmigrant or immigrant classification, in order to facilitate the applicant's ability to oversee and grow the start-up entity. If any individual believes this rule imposes a significant economic impact, that individual could simply choose not to seek parole under the rule and thus incur no economic impact. As discussed previously, this rule imposes direct filing costs of \$1,285 (which includes the \$1,200 application fee and the \$85 biometrics fee), plus \$194 in time-related opportunity costs for those individuals who do choose to apply for parole as entrepreneurs under the rule. This cost is relatively minor when considering the costs of starting up a new business and the capital necessary to start a business.

Under the general term "entrepreneur," DHS includes those who desire to form firms with investment funds from certain U.S. investors. For purposes of the RFA, the regulatory requirements place compliance costs and establish eligibility criteria for the individual requesting consideration for parole under this rule. DHS believes that the costs of application for parole will burden the individual applicant, and

not the entrepreneurial venture (firm). This rule will not alter or change the normal procedure for fundraising or other start-up administrative costs that occur in forming a business entity. Such costs are not direct costs of this rule and could include, but are not limited to, business application fees, legal fees, and licensing that precede significant infusions of investment, the latter of which are primarily utilized for operational and capital expenses in order to produce goods or services.

It is possible that some of the 2,940 estimated entrepreneurs who could be eligible for parole annually could involve business structures in which the filing fees are paid by a business entity. In the event that small business entities are impacted by this rule because they choose to pay the filing fees on behalf of an individual entrepreneur, DHS believes that the filing cost of \$1,285 per application will be insignificant compared to such entities' annual gross revenues, potential for revenue, and other economic activity.

For businesses that may pay the filing costs, the expected impact to such businesses will be small. For businesses that utilize either the minimum threshold of \$100,000 for a qualifying government grant or award or \$250,000 in capital investment to source the filing costs, such costs will constitute 1.3 percent and 0.4 percent, respectively, of the total capital amount. These relatively low cost proportions apply to those firms that only obtain the minimum investment amounts and have no other source of funding or revenues. In addition, DHS analyzed the cost impact relative to more typical RFA indices. DHS analysis of Census Bureau data on the smallest firms found that the average revenue based on sales receipts for firms with no paid employees is \$309,000, while the average for firms with one to four paid employees is \$411,000.<sup>98</sup> The filing cost relative to these averages is 0.42 percent and 0.31 percent, respectively.

DHS also analyzed the average revenue for new firms. Since the rule defines a new firm as one that is less than five years old at the time the initial parole application is filed, DHS grouped private sector firms for the 2012 survey as those responding that the year of

<sup>98</sup>The data utilized for the analysis are found in the SBO Table SB1200CSA09, "Statistics for All U.S. Firms with Paid Employees by Industry, Gender, and Employment Size of Firm for the U.S. and States: 2012, 2012 Survey of Business Owners: <http://census.gov/library/publications/2012/econ/2012-sbo.html>. The file location is: [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO\\_2012\\_00CSA09&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO_2012_00CSA09&prodType=table). The figures are rounded from \$309,279 and \$410,900, respectively.

establishment was either 2012, 2011, 2010, 2009, or 2008. DHS obtained the average revenue per firm and then weighted the average by the yearly proportion of firms. Based on the resulting weighted average of \$162,000, such new firms will face a filing-cost burden of 0.8 percent.<sup>99</sup> DHS notes that there is a large difference between the revenue of new firms with paid employees and those without such employees (*i.e.*, sole proprietors). For the latter, average revenues are about \$34,000, and the cost burden will be 3.8 percent. However, because a central component of this parole program requires a demonstration of significant public benefit in the form of economic activity and job growth, DHS does not anticipate that sole proprietors will be eligible to participate in this program.

In summary, DHS believes that per-applicant costs will be primarily incurred by the individual (which is not covered by the RFA), any direct cost due to this rule will be relatively minor, and these costs will only be borne by those who voluntarily choose to apply for parole under this rule. While the applicant for parole may be the owner of a firm that could be considered small within the definition of small entities established by 5 U.S.C. 601(6), DHS considers the applicants to be individuals at the point in time they are applying for parole, particularly since it is the individual and not the entity that files the application and it is the individual whose parole must provide a significant public benefit under this rule. Furthermore, even if firms do voluntarily decide to incur the compliance costs on behalf of the individual requesting consideration for parole under this rule, the only compliance costs those businesses will be permitted to incur will be the filing costs for the applications. As indicated previously, based on the comparison metric used, those costs are expected to be insignificant.

Based on the evidence presented in this RFA section and throughout this preamble, DHS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

<sup>99</sup> The data utilized for the analysis are found in the SBO Table SB1200CSB11, "Statistics for All U.S. Firms by Year the Business Was Originally Established or Self-Employment Activity Begun by Industry, Gender, Ethnicity, Race, and Veteran Status for the U.S.: 2012: 2012 Survey of Business Owners: <http://census.gov/library/publications/2012/econ/2012-sbo.html>. The file location is: [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO\\_2012\\_00CSB11&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO_2012_00CSB11&prodType=table). The average revenue figure is rounded from \$162,293.

#### *E. National Environmental Policy Act*

DHS Directive (Dir) 023–01 Rev. 01 establishes the procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA. 40 CFR parts 1500 through 1508.

The CEQ regulations allow federal agencies to establish, with CEQ review and concurrence, categories of actions ("categorical exclusions") which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(1)(iii), 1508.4. DHS Directive 023–01 Rev. 01 establishes Categorical Exclusions that DHS has found to have no such effect. Dir. 023–01 Rev. 01 Appendix A Table 1. For an action to be categorically excluded, DHS Directive 023–01 Rev. 01 requires the action to satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the Categorical Exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Dir. 023–01 Rev. 01 section V.B (1)–(3).

DHS analyzed this action and does not consider it to significantly affect the quality of the human environment. This rule provides criteria and procedures for applying the Secretary's existing statutory parole authority to entrepreneurs in a manner to assure consistency in case-by-case adjudications. DHS has determined that this rule does not individually or cumulatively have a significant effect on the human environment because it fits within two categorical exclusions under DHS Directive 023–01 Rev. 01, Appendix A, Table 1. Specifically, the rule fits within Categorical Exclusion number A3(a) for rules strictly of an administrative or procedural nature and A3(d) for rules that interpret or amend an existing regulation without changing its environmental effect.

This rule is not part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental effects. Fewer than 3,000 individuals, an insignificant number in the context of the population of the United States, are projected to receive parole through this program. Furthermore, any ventures will be governed by local, state and federal laws and regulations, including those protecting the human health and the

environment. Therefore, this rule is categorically excluded from further NEPA review.

#### *F. Executive Order 13132*

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

#### *G. Executive Order 12988*

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

#### *H. Paperwork Reduction Act*

Under the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, all Departments are required to submit to the Office of Management and Budget (OMB), for review and approval, any reporting requirements inherent in a rule. *See* Public Law 104–13, 109 Stat. 163 (May 22, 1995). This final rule involves a new information collection and makes revisions to the existing information collections as follows:

Overview of Information Collection, Application for Entrepreneur Parole, Form I–941

This final rule requires that an applicant requesting entrepreneur parole complete an Application for Entrepreneur Parole, Form I–941, and is considered a new information collection under the PRA. USCIS did receive one comment regarding the time burden of this form and, upon review of the work involved to review the form, gather necessary information to support the submission, and the time required to complete and submit the form, USCIS has revised the estimated hour burden per response to 4.7 hours.

a. *Type of information collection:* New information collection.

b. *Abstract:* This collection will be used by individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals, other than those filing an application on the basis of a material change, are subject to biometric collection in connection with the filing of the application.

c. *Title of Form/Collection:* Application for Entrepreneur Parole, Form I–941.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-941, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Businesses and other for profit; Not-for-profit Institutions.

f. *An estimate of the total annual numbers of respondents:* 2,940.

g. *Hours per response:* The estimated hour per response for Form I-941 is 4.7 hours; the estimated hour burden per response for the biometric processing is 1.17 hours.

h. *Total Annual Reporting Burden:* The total estimated annual hour burden associated with this collection is 17,258 hours.

Overview of Information Collection, Application for Travel Document Form I-131, OMB Control No. 1615-0013

DHS is revising this collection by including spouses and children seeking parole on the basis of an entrepreneur parolee.

In addition to revising the form and form instructions, DHS is revising the estimate of total burden hours has increased due to the addition of this new population of Application for Travel Document, Form I-131, filers, and the increase of burden hours associated with the collection of biometrics from these applicants.

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This collection will be used by dependents of individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals are subject to biometric collection in connection with the filing of the application.

c. *Title of Form/Collection:* Application for Travel Document, Form I-131.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Application for Travel Document, Form I-131, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Individuals or households.

f. *An estimate of the total annual numbers of respondents:* 594,324.

The total number of respondents includes the additional population of 3,234 individuals as estimated previously in the analysis in Section IV.C.

g. *Hours per response:* The estimated hour per response for Form I-131 Supplement is 1.9 hours; the estimated hour burden per response for the biometric processing is 1.17 hours; the estimated hour burden per response for the passport-style photographs is .5 hours.

h. *Total Annual Reporting Burden:* The total estimated annual hour burden associated with this collection is 1,372,928 hours.

Overview of Information Collection, Employment Eligibility Verification, Form I-9, OMB Control No. 1615-0047

In accordance with new 8 CFR 274a.2(b)(1)(v)(A)(5), DHS is revising the Employment Eligibility Verification, Form I-9, Lists of Acceptable Documents, List A item 5 to replace "nonimmigrant alien" with "individual," to replace "alien's nonimmigrant" with "individual," and to add "or parole" after "status" in List A item 5.b.(2). With these changes the acceptable List A document is described as the following: For an individual authorized to work for a specific employer because of his or her status or parole, a foreign passport and Form I-94 (or Form I-94A) that has the same name as the passport and has an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole. DHS is also updating the Lists of Acceptable Documents, List C so that the most current version of the certification or report of birth issued by the Department of State is acceptable for Form I-9.

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This form was developed to facilitate compliance with section 274A of the Immigration and Nationality Act, which prohibits the knowing employment of unauthorized aliens. This information collection is necessary for employers, agricultural recruiters and referrers for a fee, and state employment agencies to verify the identity and employment authorization of individuals hired (or recruited or referred for a fee, if applicable) for employment in the United States.

c. *Title of Form/Collection:* Employment Eligibility Verification.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-9, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Business or other for-profit; Individuals or households; State, local or Tribal Government.

f. *An estimate of the total annual numbers of respondents:* 78 million employers and 78 million individuals. (The total number of responses will be only 78 million responses. Each response involves an employer and an individual who is being hired.)

g. *Hours per response:*

- Time Burden for Employees—20 minutes (.33 hours) total;
- Time Burden for Employers—10 minutes (.17 hours) total;
- Time Burden for Recordkeeping—5 minutes (.08 hours) total

h. *Total Annual Reporting Burden:* Approximately 40,600,000 total annual burden hours.

Overview of Information Collection, Application for Employment Authorization, Form I-765, OMB Control No. 1615-0040

DHS is making minor revisions to the form instructions to reflect changes made by this final rule that allow spouses of an entrepreneur parolee to request employment authorization.

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This collection will be used by individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals are subject to biometric collection in connection with the filing of the application.

This form was developed for individual aliens to request employment authorization and evidence of that employment authorization. The form is being amended to add a new class of aliens eligible to apply for employment authorization, specifically a spouse of an entrepreneur parolee described as eligible for employment authorization under this rule. Supporting documentation demonstrating eligibility must be filed with the application. The form lists examples of relevant documentation.

c. *Title of Form/Collection:* Application for Employment Authorization, Form I-765.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-765, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Individuals or households.

f. *An estimate of the total annual numbers of respondents:* 2,139,523.

This total represents the aggregate estimate for this information collection, to include the additional estimate of 2,940 respondents under this rule.

g. *Hours per response:* The estimated hour per response for Form I-765 is 3.42 hours; the estimated hour burden per response for biometric processing is 1.17 hours; the estimated hour burden per response for Form I-765 WS is .5 hours; the estimated hour burden per response for passport-style photographs is .5 hours.

h. *Total Annual Reporting Burden:* The total estimated annual hour burden associated with this collection is 8,985,859 hours.

**Regulatory Amendments**

DHS adopted most of the proposed regulatory amendments without change.

**List of Subjects**

*8 CFR Part 103*

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, Immigration, Privacy, Reporting and recordkeeping requirements.

*8 CFR Part 212*

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

*8 CFR Part 274a*

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

**PART 103—IMMIGRATION BENEFITS; BIOMETRIC REQUIREMENTS; AVAILABILITY OF RECORDS**

■ 1. The authority citation for part 103 continues to read as follows:

**Authority:** 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1365b; 31 U.S.C. 9701; Pub. L. 107-296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p.166; 8 CFR part 2; Pub. L. 112-54.

■ 2. Section 103.7 is amended by adding paragraph (b)(1)(i)(KKK) to read as follows:

**§ 103.7 Fees.**

- \* \* \* \* \*
- (b) \* \* \*
- (1) \* \* \*
- (i) \* \* \*

(KKK) *Application for Entrepreneur Parole (Form I-941).* For filing an application for parole for entrepreneurs: \$1200.

\* \* \* \* \*

**PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE**

■ 3. The authority citation for part 212 is revised to read as follows:

**Authority:** 6 U.S.C. 111, 202(4) and 271; 8 U.S.C. 1101 and note, 1102, 1103, 1182 and note, 1184, 1185 note (section 7209 of Pub. L. 108-458), 1187, 1223, 1225, 1226, 1227, 1255, 1359; 8 CFR part 2.

Section 212.1(q) also issued under section 702, Pub. L. 110-229, 122 Stat. 754, 854.

■ 4. Add § 212.19 to read as follows:

**§ 212.19 Parole for entrepreneurs.**

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Entrepreneur* means an alien who possesses a substantial ownership interest in a start-up entity and has a central and active role in the operations of that entity, such that the alien is well-positioned, due to his or her knowledge, skills, or experience, to substantially assist the entity with the growth and success of its business. For purposes of this section, an alien may be considered to possess a substantial ownership interest if he or she possesses at least a 10 percent ownership interest in the start-up entity at the time of adjudication of the initial grant of parole and possesses at least a 5 percent ownership interest in the start-up entity at the time of adjudication of a subsequent period of re-parole. During the period of initial parole, the entrepreneur may continue to reduce his or her ownership interest in the start-up entity, but must, at all times during the period of initial parole, maintain at least a 5 percent ownership interest in the entity. During the period of re-parole, the entrepreneur may continue to reduce his or her ownership interest in the start-up entity, but must, at all times during the period of parole, maintain an ownership interest in the entity.

(2) *Start-up entity* means a U.S. business entity that was recently formed, has lawfully done business during any period of operation since its date of formation, and has substantial potential for rapid growth and job creation. An entity that is the basis for a request for parole under this section may be considered recently formed if it was created within the 5 years immediately preceding the filing date of the alien's initial parole request. For

purposes of paragraphs (a)(3) and (5) of this section, an entity may be considered recently formed if it was created within the 5 years immediately preceding the receipt of the relevant grant(s), award(s), or investment(s).

(3) *Qualified government award or grant* means an award or grant for economic development, research and development, or job creation (or other similar monetary award typically given to start-up entities) made by a federal, state, or local government entity (not including foreign government entities) that regularly provides such awards or grants to start-up entities. This definition excludes any contractual commitment for goods or services.

(4) *Qualified investment* means an investment made in good faith, and that is not an attempt to circumvent any limitations imposed on investments under this section, of lawfully derived capital in a start-up entity that is a purchase from such entity of its equity, convertible debt, or other security convertible into its equity commonly used in financing transactions within such entity's industry. Such an investment shall not include an investment, directly or indirectly, from the entrepreneur; the parents, spouse, brother, sister, son, or daughter of such entrepreneur; or any corporation, limited liability company, partnership, or other entity in which such entrepreneur or the parents, spouse, brother, sister, son, or daughter of such entrepreneur directly or indirectly has any ownership interest.

(5) *Qualified investor* means an individual who is a U.S. citizen or lawful permanent resident of the United States, or an organization that is located in the United States and operates through a legal entity organized under the laws of the United States or any state, that is majority owned and controlled, directly and indirectly, by U.S. citizens or lawful permanent residents of the United States, provided such individual or organization regularly makes substantial investments in start-up entities that subsequently exhibit substantial growth in terms of revenue generation or job creation. The term "qualified investor" shall not include an individual or organization that has been permanently or temporarily enjoined from participating in the offer or sale of a security or in the provision of services as an investment adviser, broker, dealer, municipal securities dealer, government securities broker, government securities dealer, bank, transfer agent or credit rating agency, barred from association with any entity involved in the offer or sale of securities or provision of such

services, or otherwise found to have participated in the offer or sale of securities or provision of such services in violation of law. For purposes of this section, such an individual or organization may be considered a qualified investor if, during the preceding 5 years:

(i) The individual or organization made investments in start-up entities in exchange for equity, convertible debt or other security convertible into equity commonly used in financing transactions within their respective industries comprising a total in such 5-year period of no less than \$600,000; and

(ii) Subsequent to such investment by such individual or organization, at least 2 such entities each created at least 5 qualified jobs or generated at least \$500,000 in revenue with average annualized revenue growth of at least 20 percent.

(6) *Qualified job* means full-time employment located in the United States that has been filled for at least 1 year by one or more qualifying employees.

(7) *Qualifying employee* means a U.S. citizen, a lawful permanent resident, or other immigrant lawfully authorized to be employed in the United States, who is not an entrepreneur of the relevant start-up entity or the parent, spouse, brother, sister, son, or daughter of such an entrepreneur. This definition shall not include independent contractors.

(8) *Full-time employment* means paid employment in a position that requires a minimum of 35 working hours per week. This definition does not include combinations of part-time positions even if, when combined, such positions meet the hourly requirement per week.

(9) *U.S. business entity* means any corporation, limited liability company, partnership, or other entity that is organized under federal law or the laws of any state, and that conducts business in the United States, that is not an investment vehicle primarily engaged in the offer, purchase, sale or trading of securities, futures contracts, derivatives or similar instruments.

(10) *Material change* means any change in facts that could reasonably affect the outcome of the determination whether the entrepreneur provides, or continues to provide, a significant public benefit to the United States. Such changes include, but are not limited to, the following: Any criminal charge, conviction, plea of no contest, or other judicial determination in a criminal case concerning the entrepreneur or start-up entity; any complaint, settlement, judgment, or other judicial or administrative determination

concerning the entrepreneur or start-up entity in a legal or administrative proceeding brought by a government entity; any settlement, judgment, or other legal determination concerning the entrepreneur or start-up entity in a legal proceeding brought by a private individual or organization other than proceedings primarily involving claims for damages not exceeding 10 percent of the current assets of the entrepreneur or start-up entity; a sale or other disposition of all or substantially all of the start-up entity's assets; the liquidation, dissolution or cessation of operations of the start-up entity; the voluntary or involuntary filing of a bankruptcy petition by or against the start-up entity; a significant change with respect to ownership and control of the start-up entity; and a cessation of the entrepreneur's qualifying ownership interest in the start-up entity or the entrepreneur's central and active role in the operations of that entity.

(b) *Initial parole*—(1) *Filing of initial parole request form*. An alien seeking an initial grant of parole as an entrepreneur of a start-up entity must file an Application for Entrepreneur Parole (Form I-941) with USCIS, with the required fees (including biometric services fees), and supporting documentary evidence in accordance with this section and the form instructions, demonstrating eligibility as provided in paragraph (b)(2) of this section.

(2) *Criteria for consideration*—(i) *In general*. An alien may be considered for parole under this section if the alien demonstrates that a grant of parole will provide a significant public benefit to the United States based on his or her role as an entrepreneur of a start-up entity.

(ii) *General criteria*. An alien may meet the standard described in paragraph (b)(2)(i) of this section by providing a detailed description, along with supporting evidence:

(A) Demonstrating that the alien is an entrepreneur as defined in paragraph (a)(1) of this section and that his or her entity is a start-up entity as defined in paragraph (a)(2) of this section; and

(B) Establishing that the alien's entity has:

(1) Received, within 18 months immediately preceding the filing of an application for initial parole, a qualified investment amount of at least \$250,000 from one or more qualified investors; or

(2) Received, within 18 months immediately preceding the filing of an application for initial parole, an amount of at least \$100,000 through one or more qualified government awards or grants.

(iii) *Alternative criteria*. An alien who satisfies the criteria in paragraph (b)(2)(ii)(A) of this section and partially meets one or both of the criteria in paragraph (b)(2)(ii)(B) of this section may alternatively meet the standard described in paragraph (b)(2)(i) of this section by providing other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

(c) *Additional periods of parole*—(1) *Filing of re-parole request form*. Prior to the expiration of the initial period of parole, an entrepreneur parolee may request an additional period of parole based on the same start-up entity that formed the basis for his or her initial period of parole granted under this section. To request such parole, an entrepreneur parolee must timely file the Application for Entrepreneur Parole (Form I-941) with USCIS, with the required fees (including biometric services fees), and supporting documentation in accordance with the form instructions, demonstrating eligibility as provided in paragraph (c)(2) of this section.

(2) *Criteria for consideration*—(i) *In general*. An alien may be considered for re-parole under this section if the alien demonstrates that a grant of parole will continue to provide a significant public benefit to the United States based on his or her role as an entrepreneur of a start-up entity.

(ii) *General criteria*. An alien may meet the standard described in paragraph (c)(2)(i) of this section by providing a detailed description, along with supporting evidence:

(A) Demonstrating that the alien continues to be an entrepreneur as defined in paragraph (a)(1) of this section and that his or her entity continues to be a start-up entity as defined in paragraph (a)(2) of this section; and

(B) Establishing that the alien's entity has:

(1) Received at least \$500,000 in qualifying investments, qualified government grants or awards, or a combination of such funding, during the initial parole period;

(2) Created at least 5 qualified jobs with the start-up entity during the initial parole period; or

(3) Reached at least \$500,000 in annual revenue in the United States and averaged 20 percent in annual revenue growth during the initial parole period.

(iii) *Alternative criteria*. An alien who satisfies the criteria in paragraph (c)(2)(ii)(A) of this section and partially meets one or more of the criteria in paragraph (c)(2)(ii)(B) of this section may alternatively meet the standard

described in paragraph (c)(2)(i) of this section by providing other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

(d) *Discretionary authority; decision; appeals and motions to reopen*—(1) *Discretionary authority.* DHS may grant parole under this section in its sole discretion on a case-by-case basis if the Department determines, based on the totality of the evidence, that an applicant's presence in the United States will provide a significant public benefit and that he or she otherwise merits a favorable exercise of discretion. In determining whether an alien's presence in the United States will provide a significant public benefit and whether the alien warrants a favorable exercise of discretion, USCIS will consider and weigh all evidence, including any derogatory evidence or information, such as but not limited to, evidence of criminal activity or national security concerns.

(2) *Initial parole.* DHS may grant an initial period of parole based on the start-up entity listed in the request for parole for a period of up to 30 months from the date the individual is initially paroled into the United States. Approval by USCIS of such a request must be obtained before the alien may appear at a port of entry to be granted parole, in lieu of admission.

(3) *Re-parole.* DHS may re-parole an entrepreneur for one additional period of up to 30 months from the date of the expiration of the initial parole period. If the entrepreneur is in the United States at the time that USCIS approves the request for re-parole, such approval shall be considered a grant of re-parole. If the alien is outside the United States at the time that USCIS approves the request for re-parole, the alien must appear at a port of entry to be granted parole, in lieu of admission.

(4) *Appeals and motions to reopen.* There is no appeal from a denial of parole under this section. USCIS will not consider a motion to reopen or reconsider a denial of parole under this section. On its own motion, USCIS may reopen or reconsider a decision to deny the Application for Entrepreneur Parole (Form I-941), in accordance with 8 CFR 103.5(a)(5).

(e) *Payment of biometric services fee and collection of biometric information.* An alien seeking parole or re-parole under this section will be required to pay the biometric services fee as prescribed by 8 CFR 103.7(b)(1)(i)(C). An alien seeking an initial grant of parole will be required to submit biometric information. An alien seeking

re-parole may be required to submit biometric information.

(f) *Limitations.* No more than three entrepreneurs may be granted parole under this section based on the same start-up entity. An alien shall not receive more than one initial grant of entrepreneur parole or more than one additional grant of entrepreneur re-parole based on the same start-up entity, for a maximum period of parole of five years.

(g) *Employment authorization.* An entrepreneur who is paroled into the United States pursuant to this section is authorized for employment with the start-up entity incident to the conditions of his or her parole.

(h) *Spouse and children.* (1) The entrepreneur's spouse and children who are seeking parole as derivatives of such entrepreneur must individually file an Application for Travel Document (Form I-131). Such application must also include evidence that the derivative has a qualifying relationship to the entrepreneur and otherwise merits a grant of parole in the exercise of discretion. A biometric services fee is required to be filed with the application. Such spouse or child will be required to appear for collection of biometrics in accordance with the form instructions or upon request.

(2) The spouse and children of an entrepreneur granted parole under this section may be granted parole under this section for no longer than the period of parole granted to such entrepreneur.

(3) The spouse of the entrepreneur parolee, after being paroled into the United States, may be eligible for employment authorization on the basis of parole under this section. To request employment authorization, an eligible spouse paroled into the United States must file an Application for Employment Authorization (Form I-765), in accordance with 8 CFR 274a.13 and form instructions. An Application for Employment Authorization must be accompanied by documentary evidence establishing eligibility, including evidence of the spousal relationship.

(4) Notwithstanding 8 CFR 274a.12(c)(11), a child of the entrepreneur parolee may not be authorized for and may not accept employment on the basis of parole under this section.

(i) *Conditions on parole.* As a condition of parole under this section, a parolee must maintain household income that is greater than 400 percent of the federal poverty line for his or her household size as defined by the Department of Health and Human Services. USCIS may impose other such

reasonable conditions in its sole discretion with respect to any alien approved for parole under this section, and it may request verification of the parolee's compliance with any such condition at any time. Violation of any condition of parole may lead to termination of the parole in accordance with paragraph (k) of this section or denial of re-parole.

(j) *Reporting of material changes.* An alien granted parole under this section must immediately report any material change(s) to USCIS. If the entrepreneur will continue to be employed by the start-up entity and maintain a qualifying ownership interest in the start-up entity, the entrepreneur must submit a form prescribed by USCIS, with any applicable fee (not including any biometric fees), in accordance with the form instructions to notify USCIS of the material change(s). The entrepreneur parolee must immediately notify USCIS in writing if he or she will no longer be employed by the start-up entity or ceases to possess a qualifying ownership stake in the start-up entity.

(k) *Termination of parole*—(1) *In general.* DHS, in its discretion, may terminate parole granted under this section at any time and without prior notice or opportunity to respond if it determines that the alien's continued parole in the United States no longer provides a significant public benefit. Alternatively, DHS, in its discretion, may provide the alien notice and an opportunity to respond prior to terminating the alien's parole under this section.

(2) *Automatic termination.* Parole granted under this section will be automatically terminated without notice upon the expiration of the time for which parole was authorized, unless the alien timely files a non-frivolous application for re-parole. Parole granted under this section may be automatically terminated when USCIS receives written notice from the entrepreneur parolee that he or she will no longer be employed by the start-up entity or ceases to possess a qualifying ownership stake in the start-up entity in accordance with paragraph (j) of this section. Additionally, parole of the spouse or child of the entrepreneur will be automatically terminated without notice if the parole of the entrepreneur has been terminated. If parole is terminated, any employment authorization based on that parole is automatically revoked.

(3) *Termination on notice.* USCIS may terminate on notice or provide the entrepreneur or his or her spouse or children, as applicable, written notice of

its intent to terminate parole if USCIS believes that:

(i) The facts or information contained in the request for parole were not true and accurate;

(ii) The alien failed to timely file or otherwise comply with the material change reporting requirements in this section;

(iii) The entrepreneur parolee is no longer employed in a central and active role by the start-up entity or ceases to possess a qualifying ownership stake in the start-up entity;

(iv) The alien otherwise violated the terms and conditions of parole; or

(v) Parole was erroneously granted.

(4) *Notice and decision.* A notice of intent to terminate issued under this paragraph should generally identify the grounds for termination of the parole and provide a period of up to 30 days for the alien's written rebuttal. The alien may submit additional evidence in support of his or her rebuttal, when applicable, and USCIS will consider all relevant evidence presented in deciding whether to terminate the alien's parole. Failure to timely respond to a notice of intent to terminate will result in termination of the parole. When a charging document is served on the alien, the charging document will constitute written notice of termination of parole (if parole has not already been terminated), unless otherwise specified. Any further immigration and removal actions will be conducted in accordance with the Act and this chapter. The decision to terminate parole may not be appealed. USCIS will not consider a motion to reopen or reconsider a decision to terminate parole under this section. On its own motion, USCIS may reopen or reconsider a decision to terminate.

(l) *Increase of investment and revenue amount requirements.* The investment and revenue amounts in this section will be automatically adjusted every 3 years by the Consumer Price Index and posted on the USCIS Web site at [www.uscis.gov](http://www.uscis.gov). Investment and revenue amounts adjusted under this paragraph will apply to all applications filed on or after the beginning of the fiscal year for which the adjustment is made.

**PART 274a—CONTROL OF EMPLOYMENT OF ALIENS**

■ 5. The authority citation for part 274a continues to read as follows:

**Authority:** 8 U.S.C. 1101, 1103, 1324a; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101-410, 104 Stat. 890, as amended by Pub. L. 114-74, 129 Stat. 599.

- 6. Section 274a.2 is amended by:
  - a. Revising paragraphs (b)(1)(v)(A)(5) and (b)(1)(v)(C)(2);
  - b. Removing paragraph (b)(1)(v)(C)(3); and
  - c. Redesignating paragraphs (b)(1)(v)(C)(4) through (8) as paragraphs (b)(1)(v)(C)(3) through (7).

The revisions read as follows:

**§ 274a.2 Verification of identity and employment authorization.**

- \* \* \* \* \*
- (b) \* \* \*
- (1) \* \* \*
- (v) \* \* \*
- (A) \* \* \*

(5) In the case of an individual who is employment-authorized incident to status or parole with a specific employer, a foreign passport with an Arrival/Departure Record, Form I-94 (as defined in 8 CFR 1.4) or Form I-94A, bearing the same name as the passport and containing an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole;

- \* \* \* \* \*
- (C) \* \* \*

(2) Certification or report of birth issued by the Department of State, including Forms FS-545, DS-1350, FS-240;

- \* \* \* \* \*

- 7. Section 274a.12 is amended by:
  - a. Revising paragraph (b) introductory text;
  - b. Removing the word "or" at the end of paragraph (b)(24);
  - c. Removing the period at the end of paragraph (b)(25) and adding "; or" in its place;
  - d. Adding and reserving paragraphs (b)(26) through (36);
  - e. Adding paragraph (b)(37);
  - f. Revising paragraph (c)(11); and
  - g. Adding paragraph (c)(34).

The revisions and additions read as follows:

**§ 274a.12 Classes of aliens authorized to accept employment.**

- \* \* \* \* \*

(b) *Aliens authorized for employment with a specific employer incident to*

*status or parole.* The following classes of aliens are authorized to be employed in the United States by the specific employer and subject to any restrictions described in the section(s) of this chapter indicated as a condition of their parole or of their admission in, or subsequent change to, the designated nonimmigrant classification. An alien in one of these classes is not issued an employment authorization document by DHS:

- \* \* \* \* \*

(37) An alien paroled into the United States as an entrepreneur pursuant to 8 CFR 212.19 for the period of authorized parole. An entrepreneur who has timely filed a non-frivolous application requesting re-parole with respect to the same start-up entity in accordance with 8 CFR 212.19 prior to the expiration of his or her parole, but whose authorized parole period expires during the pendency of such application, is authorized to continue employment with the same start-up entity for a period not to exceed 240 days beginning on the date of expiration of parole. Such authorization shall be subject to any conditions and limitations on such expired parole. If DHS adjudicates the application prior to the expiration of this 240-day period and denies the application for re-parole, the employment authorization under this paragraph shall automatically terminate upon notification to the alien of the denial decision.

(c) \* \* \*

(11) Except as provided in paragraphs (b)(37) and (c)(34) of this section and § 212.19(h)(4) of this chapter, an alien paroled into the United States temporarily for urgent humanitarian reasons or significant public benefit pursuant to section 212(d)(5) of the Act.

- \* \* \* \* \*

(34) A spouse of an entrepreneur parolee described as eligible for employment authorization in § 212.19(h)(3) of this chapter.

- \* \* \* \* \*

**Jeh Charles Johnson,**  
*Secretary of Homeland Security.*  
 [FR Doc. 2017-00481 Filed 1-13-17; 8:45 am]  
**BILLING CODE 9111-97-P**





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Part VI

## Department of Transportation

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Federal Motor Carrier Safety Administration

49 CFR Parts 360, 365, et al.

Unified Registration System; Suspension of Effectiveness; Final Rule

**DEPARTMENT OF TRANSPORTATION****Federal Motor Carrier Safety Administration**

**49 CFR Parts 360, 365, 366, 368, 385, 387, and 390**

[Docket No. FMCSA–1997–2349]

RIN 2126–AC00

**Unified Registration System; Suspension of Effectiveness**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Final rule; suspension of effective date and temporary final rule.

**SUMMARY:** The FMCSA suspends its regulations requiring existing interstate motor carriers, freight forwarders, brokers, intermodal equipment providers (IEPs), hazardous materials safety permit (HMSP) applicants, and cargo tank facilities under FMCSA jurisdiction to submit required registration and biennial update information to the Agency via a new electronic on-line Unified Registration System (URS). During this suspension, entities needing to file will follow the same procedures and forms used to submit information to FMCSA as they do today.

**DATES:** *Effective Dates:* This rule is effective January 14, 2017.

*Comment Dates:* Petitions for reconsideration must be received by February 16, 2017.

**ADDRESSES:** Petitions for reconsideration must be submitted to: Administrator, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

All background documents, comments, and materials related to this rule may be viewed in docket number FMCSA–1997–2349 using either of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

- Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

**FOR FURTHER INFORMATION CONTACT:** Mr. Kenneth Riddle, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by telephone at (202) 366–9616 or via email at [kenneth.riddle@dot.gov](mailto:kenneth.riddle@dot.gov). Office hours are from 8:00 a.m. to 4:30 p.m. ET, Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Preamble Table of Contents**

- I. Public Participation
  - A. Viewing Comments and Documents
  - B. Privacy Act
- II. Acronyms and Abbreviations
- III. Executive Summary
- IV. Background
  - A. Legal Authority
  - B. Regulatory History
- V. Section-by-Section Analysis
  - A. Part 360, Fees for Motor Carrier Registration and Insurance
  - B. Part 365, Rules Governing Applications for Operating Authority
  - C. Part 366, Designation of Process Agent
  - D. Part 368, Application for a Certificate of Registration to Operate in Municipalities in the United States on the United States-Mexico International Border or within the Commercial Zones of Such Municipalities
  - E. Part 385, Safety Fitness Procedures
  - F. Part 387, Minimum Levels of Financial Responsibility for Motor Carriers
  - G. Part 390, Federal Motor Carrier Safety Regulations, General
  - H. Part 392, Driving of Commercial Motor Vehicles
- VI. Rulemaking Analyses and Notices
  - A. Executive Order 12866 and Executive Order 13563
  - B. Regulatory Flexibility Act
  - C. Unfunded Mandates Reform Act of 1995
  - D. National Environmental Policy Act
  - E. Paperwork Reduction Act
  - F. Executive Order 12630 (Taking of Private Property)
  - G. Executive Order 12988 (Civil Justice Reform)
  - H. Executive Order 13045 (Protection of Children)
  - I. Executive Order 13132 (Federalism)
  - J. Executive Order 12372 (Intergovernmental Review)
  - K. Executive Order 13211 (Energy Supply, Distribution, or Use)
  - L. Privacy Impact Analysis

**I. Public Participation****A. Viewing Comments and Documents**

To view comments, as well as documents identified in this preamble as available in the docket, go to <http://www.regulations.gov> and click on the “Read Comments” box in the upper right hand side of the screen. Then, in the “Keyword” box, insert “FMCSA–1997–2349” and click “Search.” Next, click “Open Docket Folder” in the “Actions” column. Finally, in the “Title” column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

**B. Privacy Act**

All comments received are posted without change to <http://www.regulations.gov>. Anyone is able to search the electronic form for all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or other organization). You may review DOT’s complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdf/E-785.pdf>.

**II. Acronyms and Abbreviations**

APA Administrative Procedure Act  
 ANPRM Advance Notice of Proposed Rulemaking  
 ASCII American Standard Code Information Interchange  
 BI&PD Bodily Injury & Property Damage  
 CAA Clean Air Act  
 CE Categorical Exclusion  
 CFR Code of Federal Regulations  
 CMV Commercial motor vehicle  
 USDOT/DOT U.S. Department of Transportation  
 EMAIL Electronic Mail  
 E.O. Executive Order  
 FMCSA Federal Motor Carrier Safety Administration  
 FF Freight Forwarder  
 FMVSS Federal Motor Vehicle Safety Standard  
 HHGFF Household Goods Freight Forwarder  
 ICCTA ICC Termination Act of 1995  
 IEP Intermodal Equipment Provider  
 GCWR Gross Combination Weight Rating  
 GVW Gross Vehicle Weight  
 GVWR Gross Vehicle Weight Rating  
 HMSP Hazardous Materials Safety Permit  
 HMR Hazardous Material Regulations, 49 CFR parts 100 through 185  
 MC Motor Carrier  
 MC–ECI Office of Enforcement and Compliance, Insurance Compliance Division  
 MCMIS Motor Carrier Management Information System  
 MC–RI Office of Information Technology  
 MC–RIS Office of Data Analysis and Information Systems  
 MC–RS Office of Registration and Safety Information  
 MX Mexico Owned or Controlled  
 NEPA National Environmental Policy Act of 1969  
 NNA Non-North America-Domiciled Motor Carrier  
 NPRM Notice of Proposed Rulemaking  
 OMB Office of Management and Budget  
 PHMSA Pipeline and Hazardous Materials Safety Administration  
 PIA Privacy Impact Assessment  
 PII Personally Identifiable Information  
 PRISM Performance and Registration Information Systems Management  
 RFA Regulatory Flexibility Act  
 RQ Reportable Quantity

SAFETEA—LU Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Public Law 109–59, 119 Stat. 1714, August 10, 2005

SCAC Standard Carrier Alpha Code

SSRS Single State Registration System

URS Unified Registration System

URS–1 Unified Registration System Final Rule, 78 FR 52608 (Aug. 23, 2013), as amended at 80 FR 63695, October 21, 2015, and at 81 FR 49553, July 28, 2016

VIN Vehicle Identification Number

### III. Executive Summary

This final rule is being issued to further delay the effective and compliance dates of the Unified Registration System final rule (URS 1 final rule), issued on August 23, 2013 and revised as noted below in the Regulatory History section. The URS 1 final rule was issued to improve the registration process for motor carriers, property brokers, freight forwarders, Intermodal Equipment Providers (IEPs), hazardous materials safety permit (HMSP) applicants, and cargo tank facilities required to register with FMCSA, and streamline the existing Federal registration processes to ensure the Agency can more efficiently track these entities. FMCSA is extending the implementation date of the final stage of the URS 1 final rule beyond January 14, 2017 because additional time is needed to securely migrate data from multiple legacy platforms into a new central database and to conduct further compatibility testing with its State partners. The Agency recently migrated its information technology systems to a “cloud” environment. This migration effort was a necessary step in order to provide a foundation to successfully implement URS.

By moving the implementation date, FMCSA is providing its State partners more time to develop, update, and verify data connectivity and system reliability. The additional time will also enable the Agency to conduct more thorough training and to implement broader outreach and education activities that will provide for a seamless transition.

Due to the numerous revisions and corrections that have been made to the URS 1 final rule, FMCSA, in consultation with the Office of the Federal Register (OFR), is allowing the URS 1 rule to come into effect, immediately suspending it, and replacing it with temporary regulations. FMCSA intends to lift the suspension once the technology to implement URS 1 is complete, and effectively replace the temporary regulations with the URS 1 final rule, as issued on August 23, 2013. FMCSA and the OFR have determined that this procedure will

result in a compilation of rules that is relatively easy to understand and follow. The temporary provisions read almost exactly as the regulations in existence on January 13, 2017 (the day before URS 1 becomes effective). Their only differences are the “T” notation in their section designation, which denotes them as temporary provisions within the Code of Federal Regulations, and new paragraph designations in some cases, to align with current guidelines for publication in the CFR.

### IV. Background

#### A. Legal Authority

FMCSA relies upon the same legal authority cited in the August 23, 2013, Unified Registration System final rule (URS 1).<sup>1</sup> The Agency suspends those portions of the URS 1 final rule that will become effective on January 14, 2017, and replaces them with the provisions in effect on January 13, 2017. Because there are no substantive changes to the content of the 2013 final rule, nor to the previous provisions, we will not expand upon the previous legal authority discussion presented in the URS 1 final rule.<sup>2</sup>

The Administrative Procedure Act (APA) (5 U.S.C. 551-706) specifically provides exceptions to its notice and public comment rulemaking requirements where the Agency finds there is good cause (and incorporates the finding and a brief statement of reasons therefore in the rules issued) to dispense with them. Generally, good cause exists where the Agency determines that notice and public procedures are impractical, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B)). This URS final rule is being issued to, in effect, delay the effective date of the original URS 1 final rule. FMCSA will not have the technological ability to support the changes made by the August 23, 2013, final rule by the final rule’s current effective date (January 14, 2017), which would make it impossible for motor carriers to comply with the regulations. If FMCSA does not suspend these regulations and replace them with temporary provisions, existing motor carriers would find themselves unable to obtain a USDOT number, request additional registration, or file evidence of meeting financial responsibility requirements, among other things. The motor carrier registration process would grind to a halt, likely posing significant harm to motor carriers, other FMCSA-regulated entities, drivers, and those

who use their services. For these reasons, FMCSA finds good cause to dispense with notice and public comment on this final rule, as providing for public notice and comment would be contrary to the public interest.

For these same reasons, and also pursuant to the APA (5 U.S.C. 553 (d)(3)), this final rule will be effective on January 14, 2017. Delaying the effective date for 30 days after publication would result in the URS 1 rule remaining in effect, causing the same complications described above.

#### B. Regulatory History

The Federal Highway Administration (FMCSA’s predecessor agency) issued an advance notice of proposed rulemaking (ANPRM), announcing plans to develop a single, online, Federal information system in August 1996.<sup>3</sup> The ANPRM solicited specific detailed information from the public about each of the systems to be replaced by the URS, the conceptual design of the URS, uses and users of the information to be collected, and potential costs.

On May 19, 2005, FMCSA published an NPRM describing a proposal to merge all of the prescribed information systems except the Single State Registration System (SSRS) into a unified, online Federal system.<sup>4</sup> The Agency subsequently revised the May 2005 proposal in an October 26, 2011, SNPRM to incorporate new congressionally mandated provisions in SAFETEA—LU,<sup>5</sup> and modified certain proposals in response to comments to the NPRM.<sup>6</sup> The SNPRM also included changes necessitated by final rules published subsequent to publication of the NPRM that directly impacted the URS. In the SNPRM, the Agency substantially altered the regulatory drafting approach proposed in the NPRM by creating a straightforward requirement for all entities to register and biennially update registration information under the new URS and by compiling a centralized cross-reference to existing safety and commercial regulations necessary for compliance with the registration requirements. The Agency abandoned previous efforts to reorganize all registration and new entrant requirements under a single part

<sup>3</sup> *Advance Notice of Proposed Rulemaking, Motor Carrier Replacement Information/Registration System*, 61 FR 43816 (Aug. 26, 1996).

<sup>4</sup> *Notice of Proposed Rulemaking, Unified Registration System*, 70 FR 28990 (May 19, 2005).

<sup>5</sup> *Safe, Accountable, Flexible, and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA—LU)*, Public Law 109–59, 119 Stat. 1714, August 10, 2005.

<sup>6</sup> *Supplemental Notice of Proposed Rulemaking, Unified Registration System*, 76 FR 66506 (Oct. 26, 2011).

<sup>1</sup> *Final Rule, Unified Registration System*, 78 FR 52608 (August 23, 2013).

<sup>2</sup> *Id.* at 52615.

under title 49, Code of Federal Regulations (CFR) chapter III. FMCSA issued the final rule for URS (“URS 1”) on August 23, 2013.<sup>7</sup> That rule had an effective date of October 23, 2015.<sup>8</sup>

On October 21, 2015, FMCSA published a final rule delaying the URS 1 effective date until September 30, 2016.<sup>9</sup> This delay, however, included several new, temporary regulations which directed new applicants (who were also defined in the final rule) to utilize the online MCSA-1 application in order to request registration and a USDOT number. On July 28, 2016, FMCSA again delayed the URS 1 effective dates, this time until January 14, 2017, via a correction to the October 21, 2015 final rule document.<sup>10</sup> That correction also extended the effective period for the temporary provisions from the October 21, 2015 document.

**V. Section-by-Section Analysis**

This rule amends 49 CFR part 360 in reference to fees; part 365 procedures governing applications for operating authority and transfers of operating authority; part 366 procedures for designations of process agents; part 368 procedures governing applications to operate in municipalities in the United States on the United States-Mexico international border or within the commercial zones of such municipalities; part 385 safety fitness procedures; part 387 levels of financial responsibility; and part 390 general applicability of the FMCSRs. In each part, the provisions enacted by the URS 1 final rule that go into effect January 14, 2017, are being immediately suspended and replaced by temporary provisions that contain the same

requirements in place on January 13, 2017. The only changes being made to the regulatory text are to replace internal cross references to CFR parts or sections that are either being suspended or have been removed with the corresponding temporary provision (found in the table below), and to include paragraph designations on previously undesignated text, in order to align with current guidelines for publication in the CFR. The following table lays out those provisions being suspended, and the corresponding temporary provision being added to replace the suspended regulations. Note that in some cases, there is not a corresponding suspended or temporary provision, as the URS 1 final rule both added new regulatory sections and removed sections without replacing them.

Suspended CFR part or section	Corresponding temporary CFR section(s)	Section title
360.1	360.1T	Fees for registration-related services.
360.3	360.3T	Filing fees.
360.5	360.5T	Updating user fees.
365.101	365.101T	Applications governed by these rules.
365.103	365.103T	Modified procedure.
365.105	365.105T	Starting the application process: Form OP-1.
N/A	365.106T	Starting the application process: URS online application.
365.107	365.107T	Types of applications.
365.109	365.109T	FMCSA review of the application.
365.111	365.111T	Appeals to rejections of the application.
365.119	365.119T	Opposed applications.
365.201	365.201T	Definitions.
365.203	365.203T	Time for filing.
365.301	365.301T	Applicable rules.
Part 365, Subpart D	365.401T, 365.403T, 365.405T, 365.407T, 365.409T, 365.411T, 365.413T.	Transfer of Operating Rights Under 49 U.S.C. 10926.
365.507	365.507T	FMCSA action on the application.
365.509	365.509T	Requirement to notify FMCSA of change in applicant information.
366.1	366.1T	Applicability.
366.2	366.2T	Form of designation.
366.3	366.3T	Eligible persons.
366.4	366.4T	Required States.
366.5	366.5T	Blanket designations.
366.6	366.6T	Cancellation or change.
N/A	368.3-1T <sup>11</sup>	Starting the application process: URS online application.
368.3	368.3T	Applying for a certificate of registration.
368.4	368.4T	Requirement to notify FMCSA of change in applicant information.
368.8	368.8T	Appeals.
385.301	385.301T	What is a motor carrier required to do before beginning interstate operations?
385.303	385.303T	How does a motor carrier register with the FMCSA?
385.305	385.305T	What happens after the FMCSA receives a request for new entrant registration?
385.329	385.329T	May a new entrant that has had its USDOT new entrant registration revoked and its operations placed out of service reapply?
385.405	385.405T	How does a motor carrier apply for a safety permit?
385.409	385.409T	When may a temporary safety permit be issued to a motor carrier?
385.419	385.419T	How long is a safety permit effective?
385.421	385.421T	Under what circumstances will a safety permit be subject to revocation or suspension by FMCSA?
385.603	385.603T	Application.

<sup>7</sup> Final Rule, Unified Registration System, 78 FR 52608 (Aug. 23, 2013).

<sup>8</sup> Certain provisions in the URS 1 final rule became effective on November 1, 2013. Specifically, the changes to 49 CFR 390.19 and 392.2b came into

effect earlier than the rest of the final rule. The changes to 49 CFR 366.2 were not effective until April 25, 2016.

<sup>9</sup> Final Rule; extension of effective dates, Unified Registration System, 80 FR 63695 (Oct. 21, 2015).

The delay did not impact those portions of the URS 1 final rule that had already become effective.

<sup>10</sup> Final Rule; correction, Unified Registration System; Correction, 81 FR 49553 (Jul. 28, 2016).

Suspended CFR part or section	Corresponding temporary CFR section(s)	Section title
385.607 .....	385.607T .....	FMCSA action on the application.
385.609 .....	385.609T .....	Requirement to notify FMCSA of change in applicant information.
385.713 .....	385.713T .....	Reapplying for new entrant registration.
387.19 .....	N/A .....	Electronic filing of surety bonds, trust fund agreements, certificates of insurance and cancellations.
387.33 .....	387.33T .....	Financial responsibility, minimum levels.
387.43 .....	N/A .....	Electronic filing of surety bonds, trust fund agreements, certificates of insurance and cancellations.
387.301 .....	387.301T .....	Surety bond, certificate of insurance, or other securities.
387.303 .....	387.303T .....	Security for the protection of the public: Minimum limits.
387.313 .....	387.313T .....	Forms and procedures.
387.323 .....	387.323T .....	Electronic filing of surety bonds, trust fund agreements, certificates of insurance and cancellations.
387.403 .....	387.403T .....	General requirements.
387.413 .....	387.413T .....	Forms and procedures.
387.419 .....	387.419T .....	Electronic filing of surety bonds, certificates of insurance and cancellations.
390.3 .....	390.3T .....	General applicability.
390.5 .....	390.5T .....	Definitions.
390.19 .....	390.19T .....	Motor carrier identification reports for certain Mexico-domiciled motor carriers.
390.21 .....	390.21T .....	Marking of self-propelled commercial motor vehicles (CMVs) and intermodal equipment.
390.40 .....	390.40T .....	What responsibilities do intermodal equipment providers have under the Federal Motor Carrier Safety Regulations (49 CFR parts 350 through 399)?
Part 390, Subpart E .....	390.200T .....	USDOT Registration.

## VI. Rulemaking Analyses and Notices

### A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures as Supplemented by E.O. 13563

FMCSA has determined that this final rule, essentially delaying the effective date of the URS rules, is not a significant regulatory action within the meaning of E.O. 12866, as supplemented by E.O. 13563, or within the meaning of DOT regulatory policies and procedures. The Agency does not expect this action to have any new costs; this action suspending the provisions of the August 23, 2013 and reinstating the pre-existing registration provisions will delay the associated costs of the August 23, 2013, final rule. As discussed previously, this action is necessary because the URS 1 technological solution, required to implement the URS 1 final rule, is not ready. Not suspending the URS 1 final rule may result in additional costs, as allowing the URS 1 final rule to come into effect without having the required technological pieces (such as the URS online application and the integrated database required by statute) would require motor carriers, freight forwarders, brokers, and others to use a system that does not exist, with no

alternative for seeking registration authorities. This could lead to a delay in processing registrations, which could then impact the applicants. Suspending the URS final rule and temporarily reinstating the pre-existing rules avoids these potential costs, without adding new costs over what was originally estimated in the August 2013 RIA. The August 2013 RIA can be found in the docket for this final rule.

### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601–612), FMCSA is not required to complete a regulatory flexibility analysis. This is because this rule does not require publication of a general notice of proposed rulemaking. However, in compliance with the RFA, FMCSA has evaluated the effects of this final rule on small entities, and determined that delaying the effective date for the URS 1 final rule will not result in a significant economic impact on a substantial number of small entities. Accordingly, the Administrator of FMCSA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

### C. Unfunded Mandates Reform Act of 1995

This final rule will not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532, *et seq.*), that will

result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$156 million (which is the value of \$100 million adjusted for inflation) or more in any one year.

### D. National Environmental Policy Act

The Agency analyzed this final rule for the purpose of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined under our environmental procedures Order 5610.1, issued March 1, 2004 (69 FR 9680), that this action is categorically excluded (CE) under Appendix 2, paragraphs 6(e), 6(h) and 6(y)(2) of the Order from further environmental documentation. The CE under Appendix 2, paragraph 6(e) relates to establishing regulations and actions taken pursuant to the requirements concerning applications for operating authority and certificates of registration. The CE under Appendix 2, paragraph 6(h), relates to establishing regulations and actions taken pursuant to the requirements implementing procedures to collect fees that will be charged for motor carrier registrations and insurance for the following activities: (1) Application filings; (2) records searches; and (3) reviewing, copying, certifying, and related services. The CE under Appendix 2, paragraph 6(y)(2), addresses regulations implementing motor carrier identification and registration reports. In addition, the Agency believes that

<sup>11</sup> This abnormal numbering scheme represents a slight change to the regulation. It is being made because without it, there would be two separate provisions designated as 49 CFR 368.3T, which is not allowable.

this rule includes no extraordinary circumstances that will have any effect on the quality of the human environment. Thus, this rule does not require an environmental assessment or an environmental impact statement.

FMCSA also has analyzed this rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 7401 *et seq.*), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement because it involves policy development and rulemaking activities regarding registration of regulated entities with FMCSA for commercial, safety and financial responsibility purposes. See 40 CFR 93.153(c)(2)(vi). The changes would not result in any emissions increases, nor will they have any potential to result in emissions that are above the general conformity rule's de minimis emission threshold levels. Moreover, it is reasonably foreseeable that the actions will not increase total CMV mileage or change the routing of CMVs, how CMVs operate, or the CMV fleet-mix of motor carriers.

#### *E. Paperwork Reduction Act*<sup>12</sup>

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), a Federal Agency must obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. The FMCSA analyzed the August 23, 2013, final rule and determined that its implementation would streamline the information collection burden on motor carriers and other regulated entities, relative to the baseline, or current paperwork collection processes. This included streamlining the FMCSA registration, insurance, and designation of process agent filing processes and implementing mandatory electronic online filing of these applications, as well as eliminating some outdated filing requirements. A full analysis of the impacted collections of information, both existing and new, can be found in that final rule,<sup>13</sup> a copy of which is in the docket for this final rule. This final rule makes no changes to the collections described in that final rule.

#### *F. Executive Order 12630 (Taking of Private Property)*

This final rule will not result in a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental

Actions and Interference with Constitutionally Protected Property Rights.

#### *G. Executive Order 12988 (Civil Justice Reform)*

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### *H. Executive Order 13045 (Protection of Children)*

Executive Order 13045, “Protection of Children from Environmental Health Risks and Safety Risks” (April 23, 1997, 62 FR 19885), requires that agencies issuing economically significant rules, which also concern an environmental health or safety risk that an Agency has reason to believe may disproportionately affect children, must include an evaluation of the environmental health and safety effects of the regulation on children. Section 5 of Executive Order 13045 directs an Agency to submit for a covered regulatory action an evaluation of its environmental health or safety effects on children. This final rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

#### *I. Executive Order 13132 (Federalism)*

This rule has been analyzed in accordance with the principles and criteria in Executive Order 13132, dated August 4, 1999 (64 FR 43255, August 10, 1999). The FMCSA consulted with State licensing agencies participating in its PRISM Program to discuss anticipated impacts of the May 2005 NPRM upon their operations. The Agency has taken into consideration their comments in its decision-making process for this rule. Thus, FMCSA has determined that this rule will not have significant Federalism implications or limit the policymaking discretion of the States.

#### *J. Executive Order 12372 (Intergovernmental Review)*

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this final rule.

#### *K. Executive Order 13211 (Energy Supply, Distribution, or Use)*

FMCSA has analyzed this rule under Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use,” and has determined that this is not a significant energy action within the meaning of section 4(b) of the Executive Order. This final rule is not economically significant, and will not have a significant adverse effect on the supply, distribution, or use of energy.

#### *L. Privacy Impact Analysis*

The FMCSA conducted a privacy impact assessment (PIA) of the August 23, 2013, final rule as required by section 522(a)(5) of division H of the FY 2005 Omnibus Appropriations Act, Public Law 108–447, 118 Stat. 3268 (Dec. 8, 2004) [set out as a note to 5 U.S.C. 552a]. The assessment considered any impacts of the final rule on the privacy of information in an identifiable form and related matters. FMCSA determined that the August 23, 2013, final rule will impact the handling of personally identifiable information (PII). FMCSA also determined the risks and effects the rulemaking might have on collecting, storing, and sharing PII and examined and evaluated protections and alternative information handling processes in order to mitigate potential privacy risks. This final rule makes no changes to the information being collected, or to the manner that it is stored and shared. FMCSA believes that the PIA for the August 23, 2013, final rule adequately covers this action; that PIA remains available for review in the docket for this final rule.

#### **List of Subjects**

##### *49 CFR Part 360*

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

##### *49 CFR Part 365*

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Motor carriers, Moving of household goods.

##### *49 CFR Part 366*

Brokers, Motor carriers, Freight forwarders, Process agents.

##### *49 CFR Part 368*

Administrative practice and procedure, Insurance, Motor carriers.

##### *49 CFR Part 385*

Administrative practice and procedure, Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

<sup>12</sup> The calculations presented in this section may be subject to rounding errors.

<sup>13</sup> See 78 FR 52608, 52642.

#### 49 CFR Part 387

Buses, Freight, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Intergovernmental relations, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

#### 49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA amends 49 CFR chapter III as set forth below:

### PART 360—FEES FOR MOTOR CARRIER REGISTRATION AND INSURANCE

■ 1. The authority citation for part 360 is revised to read as follows:

**Authority:** 31 U.S.C. 9701; 49 U.S.C. 13908; and 49 CFR 1.87.

#### §§ 360.1 through 360.5 [Suspended]

■ 2. Suspend §§ 360.1 through 360.5.

■ 3. Add § 360.1T to read as follows:

#### § 360.1T Fees for registration-related services.

Certifications and copies of public records and documents on file with the Federal Motor Carrier Safety Administration will be furnished on the following basis, pursuant to the Freedom of Information Act regulations at 49 CFR part 7:

(a) Certificate of the Director, Office of Data Analysis and Information Systems, as to the authenticity of documents, \$9.00;

(b) Service involved in checking records to be certified to determine authenticity, including clerical work, etc., incidental thereto, at the rate of \$16.00 per hour;

(c) Copies of the public documents, at the rate of \$.80 per letter size or legal size exposure. A minimum charge of \$5.00 will be made for this service; and

(d) Search and copying services requiring ADP processing, as follows:

(1) A fee of \$42.00 per hour for professional staff time will be charged when it is required to fulfill a request for ADP data.

(2) The fee for computer searches will be set at the current rate for computer service. Information on those charges can be obtained from the Office of Data Analysis and Information Systems (MC-RIS).

(3) Printing shall be charged at the rate of \$.10 per page of computer

generated output with a minimum charge of \$.25. A charge of \$30 per reel of magnetic tape will be made if the tape is to be permanently retained by the requestor.

■ 4. Add § 360.3T to read as follows:

#### § 360.3T Filing fees.

(a) *Manner of payment.* (1) Except for the insurance fees described in the next sentence, all filing fees will be payable at the time and place the application, petition, or other document is tendered for filing. The service fee for insurance, surety or self-insurer accepted certificate of insurance, surety bond or other instrument submitted in lieu of a broker surety bond must be charged to an insurance service account established by the Federal Motor Carrier Safety Administration in accordance with paragraph (a)(2) of this section.

(2) *Billing account procedure.* A written request must be submitted to the Office of Enforcement and Compliance, Insurance Compliance Division (MC-ECI) to establish an insurance service fee account.

(i) Each account will have a specific billing date within each month and a billing cycle. The billing date is the date that the bill is prepared and printed. The billing cycle is the period between the billing date in one month and the billing date in the next month. A bill for each account which has activity or an unpaid balance during the billing cycle will be sent on the billing date each month. Payment will be due 20 days from the billing date. Payments received before the next billing date are applied to the account. Interest will accrue in accordance with 4 CFR 102.13.

(ii) The Debt Collection Act of 1982, including disclosure to the consumer reporting agencies and the use of collection agencies, as set forth in 4 CFR 102.5 and 102.6 will be utilized to encourage payment where appropriate.

(iii) An account holder who files a petition in bankruptcy or who is the subject of a bankruptcy proceeding must provide the following information to the Office of Enforcement and Compliance, Insurance Division (MC-ECI):

(A) The filing date of the bankruptcy petition;

(B) The court in which the bankruptcy petition was filed;

(C) The type of bankruptcy proceeding;

(D) The name, address, and telephone number of its representative in the bankruptcy proceeding; and

(E) The name, address, and telephone number of the bankruptcy trustee, if one has been appointed.

(3) Fees will be payable to the Federal Motor Carrier Safety Administration by

a check payable in United States currency drawn upon funds deposited in a United States or foreign bank or other financial institution, money order payable in United States' currency, or credit card (VISA or MASTERCARD).

(b) Any filing that is not accompanied by the appropriate filing fee is deficient except for filings that satisfy the deferred payment procedures in paragraph (a) of this section.

(c) *Fees not refundable.* Fees will be assessed for every filing in the type of proceeding listed in the schedule of fees contained in paragraph (f) of this section, subject to the exceptions contained in paragraphs (d) and (e) of this section. After the application, petition, or other document has been accepted for filing by the Federal Motor Carrier Safety Administration, the filing fee will not be refunded, regardless of whether the application, petition, or other document is granted or approved, denied, rejected before docketing, dismissed, or withdrawn.

(d) *Related or consolidated proceedings.* (1) Separate fees need not be paid for related applications filed by the same applicant which would be the subject of one proceeding. (This does not mean requests for multiple types of operating authority filed on forms in the OP-1 series under the regulations at 49 CFR part 365. A separate filing fee is required for each type of authority sought in each transportation mode, e.g., common, contract, and broker authority for motor property carriers.)

(2) Separate fees will be assessed for the filing of temporary operating authority applications as provided in paragraph (f)(6) of this section, regardless of whether such applications are related to an application for corresponding permanent operating authority.

(3) The Federal Motor Carrier Safety Administration may reject concurrently filed applications, petitions, or other documents asserted to be related and refund the filing fee if, in its judgment, they embrace two or more severable matters which should be the subject of separate proceedings.

(e) *Waiver or reduction of filing fees.* It is the general policy of the Federal Motor Carrier Safety Administration not to waive or reduce filing fees except as described as follows:

(1) Filing fees are waived for an application or other proceeding which is filed by a Federal government agency, or a State or local government entity. For purposes of this section the phrases "Federal government agency" or "government entity" do not include a quasi-governmental corporation or



government subsidized transportation company.

(2) In extraordinary situations the Federal Motor Carrier Safety Administration will accept requests for waivers or fee reductions in accordance with the following procedure:

(i) *When to request.* At the time that a filing is submitted to the Federal

Motor Carrier Safety Administration the applicant may request a waiver or reduction of the fee prescribed in this part. Such request should be addressed to the Director, Office of Data Analysis and Information Systems.

(ii) *Basis.* The applicant must show the waiver or reduction of the fee is in the best interest of the public, or that

payment of the fee would impose an undue hardship upon the requestor.

(iii) *Federal Motor Carrier Safety Administration action.* The Director, Office of Data Analysis and Information Systems, will notify the applicant of the decision to grant or deny the request for waiver or reduction.

(f) *Schedule of filing fees.*

Type of proceeding		Fee
Part I: Licensing:		
(1) .....	An application for motor carrier operating authority, a certificate of registration for certain foreign carriers, property broker authority, or freight forwarder authority.	\$300.
(2) .....	A petition to interpret or clarify an operating authority .....	3,000.
(3) .....	A request seeking the modification of operating authority only to the extent of making a ministerial correction, when the original error was caused by applicant, a change in the name of the shipper or owner of a plant site, or the change of a highway name or number.	50.
(4) .....	A petition to renew authority to transport explosives .....	250.
(5) .....	An application for authority to deviate from authorized regular-route authority.	150.
(6) .....	An application for motor carrier temporary authority issued in an emergency situation.	100.
(7) .....	Request for name change of a motor carrier, property broker, or freight forwarder.	14.
(8) .....	An application involving the merger, transfer, or lease of the operating rights of motor passenger and property carriers, property brokers, and household goods freight forwarders under 49 U.S.C. 10321 and 10926.	300.
(9)–(49) .....	[Reserved] .....	
Part II: Insurance:		
(50) .....	(i) An application for original qualification as self-insurer for bodily injury and property damage insurance (BI&PD). (ii) An application for original qualification as self-insurer for cargo insurance.	4,200.
(51) .....	A service fee for insurer, surety, or self-insurer accepted certificate of insurance, surety bond, and other instrument submitted in lieu of a broker surety bond.	420.
(52) .....	A petition for reinstatement of revoked operating authority .....	\$10 per accepted certificate, surety bond or other instrument submitted in lieu of a broker surety bond.
(53)–(79) .....	[Reserved] .....	80.
Part III: Services:		
(80) .....	Request for service or pleading list for proceedings .....	13 per list.
(81) .....	Faxed copies of operating authority to applicants or their representatives who did not receive a served copy.	5.

(g) *Returned check policy.* (1) If a check submitted to the FMCSA for a filing or service fee is dishonored by a bank or financial institution on which it is drawn, the FMCSA will notify the person who submitted the check that:

(i) All work will be suspended on the filing or proceeding, until the check is made good;

(ii) A returned check charge of \$6.00 and any bank charges incurred by the FMCSA as a result of the dishonored check must be submitted with the filing fee which is outstanding; and

(iii) If payment is not made within the time specified by the FMCSA, the proceeding will be dismissed or the filing may be rejected.

(2) If a person repeatedly submits dishonored checks to the FMCSA for filing fees, the FMCSA may notify the person that all future filing fees must be submitted in the form of a certified or

cashier's check, money order, or credit card.

■ 5. Add § 360.5T to read as follows:

**§ 360.5T Updating user fees.**

(a) *Update.* Each fee established in this part may be updated in accordance with this section as deemed necessary by the FMCSA.

(b) *Publication and effective dates.* Updated fees shall be published in the **Federal Register** and shall become effective 30 days after publication.

(c) *Payment of fees.* Any person submitting a filing for which a fee is established shall pay the fee in effect at the time of the filing.

(d) *Method of updating fees.* Each fee shall be updated by updating the cost components comprising the fee. Cost components shall be updated as follows:

(1) Direct labor costs shall be updated by multiplying base level direct labor

costs by percentage changes in average wages and salaries of FMCSA employees. Base level direct labor costs are direct labor costs determined by the cost study in Regulations Governing Fees For Service, 1 I.C.C. 2d 60 (1984), or subsequent cost studies. The base period for measuring changes shall be April 1984 or the year of the last cost study.

(2) Operations overhead shall be developed each year on the basis of current relationships existing on a weighted basis, for indirect labor applicable to the first supervisory work centers directly associated with user fee activity. Actual updating of operations overhead will be accomplished by applying the current percentage factor to updated direct labor, including current governmental overhead costs.

(3)(i) Office general and administrative costs shall be developed

each year on the basis of current levels costs, *i.e.*, dividing actual office general and administrative costs for the current fiscal year by total office costs for the office directly associated with user fee activity. Actual updating of office general and administrative costs will be accomplished by applying the current percentage factor to updated direct labor, including current governmental overhead and current operations overhead costs.

(ii) FMCSA general and administrative costs shall be developed each year on the basis of current level costs; *i.e.*, dividing actual FMCSA general and administrative costs for the current fiscal year by total agency expenses for the current fiscal year. Actual updating of FMCSA general and administrative costs will be accomplished by applying the current percentage factor to updated direct labor, including current governmental overhead, operations overhead and office general and administrative costs.

(4) Publication costs shall be adjusted on the basis of known changes in the costs applicable to publication of material in the **Federal Register** or *FMCSA Register*. (This rounding procedures excludes copying, printing and search fees.)

(e) *Rounding of updated fees.* Updated fees shall be rounded in the following manner:

- (1) Fees between \$1 and \$30 will be rounded to the nearest \$1;
- (2) Fees between \$30 and \$100 will be rounded to the nearest \$10;
- (3) Fees between \$100 and \$999 will be rounded to the nearest \$50; and
- (4) Fees above \$1,000 will be rounded to the nearest \$100.

#### **PART 365—RULES GOVERNING APPLICATIONS FOR OPERATING AUTHORITY**

■ 6. The authority citation for part 365 is revised to read as follows:

**Authority:** 5 U.S.C. 553 and 559; 49 U.S.C. 13101, 13301, 13901–13906, 13908, 14708, 31133, 31138, and 31144; 49 CFR 1.87.

#### **§§ 365.101 through 365.109— [SUSPENDED]**

■ 7. Suspend §§ 365.101 through 365.109.

■ 8. Add § 365.101T to read as follows:

#### **§ 365.101T Applications governed by these rules.**

These rules govern the handling of applications for operating authority of the following type:

(a) Applications for certificates and permits to operate as a motor common or contract carrier of property or passengers.

(b) Applications for permits to operate as a freight forwarder.

(c) [Reserved]

(d) Applications for licenses to operate as a broker of motor vehicle transportation.

(e) Applications for certificates under 49 U.S.C. 13902(b)(3) to operate as a motor carrier of passengers in intrastate commerce over regular routes if such intrastate transportation is to be provided on a route over which the carrier provides interstate transportation of passengers.

(f) [Reserved]

(g) Applications for temporary motor carrier authority.

(h) Applications for Mexico-domiciled motor carriers to operate in foreign commerce as common, contract or private motor carriers of property (including exempt items) between Mexico and all points in the United States. Under NAFTA Annex I, page I–U–20, a Mexico-domiciled motor carrier may not provide point-to-point transportation services, including express delivery services, within the United States for goods other than international cargo.

(i) Applications for non-North America-domiciled motor carriers to operate in foreign commerce as for-hire motor carriers of property and passengers within the United States.

(j) The rules in this part do not apply to “pipeline welding trucks” as defined in 49 CFR 390.38(b).

■ 9. Add § 365.103T to read as follows:

#### **§ 365.103T Modified procedure.**

The FMCSA will handle licensing application proceedings using the modified procedure, if possible. The applicant and protestants send statements made under oath (verified statements) to each other and to the FMCSA. There are no personal appearances or formal hearings.

■ 10. Add § 365.105T to read as follows:

#### **§ 365.105T Starting the application process: Form OP–1.**

(a)(1) Each applicant must file the appropriate form in the OP–1 series. Form OP–1 must be filed when requesting authority to operate as a motor property carrier, a broker of general freight, or a broker of household goods; Form OP–1(P) must be filed when requesting authority to operate as a motor passenger carrier; Form OP–1(FF) must be filed when requesting authority to operate as a freight forwarder; Form OP–1(MX) must be filed by a Mexico-domiciled motor property, including household goods, carrier, or a motor passenger carrier requesting authority to operate within

the United States; and effective December 16, 2009.

(2) Form OP–1(NNA) must be filed by a non-North America-domiciled motor property, including household goods, carrier or a motor passenger carrier requesting authority to operate within the United States. A separate filing fee in the amount set forth at 49 CFR 360.3T(f)(1) is required for each type of authority sought.

(b) Obtain forms at a FMCSA Division Office in each State or at one of the FMCSA Service Centers. Addresses and phone numbers for the Division Offices and Service Centers can be found at: <https://www.fmcsa.dot.gov/mission/field-offices>. The forms and information about filing procedures can be downloaded at: <https://www.fmcsa.dot.gov/registration/registration-forms>.

■ 11. Add § 365.106T to read as follows:

#### **§ 365.106T Starting the application process: URS online application.**

(a) Notwithstanding § 365.105T, new applicants as defined in paragraph (b) of this section must apply for a USDOT number and if applicable, operating authority by electronically filing Form MCSA–1, the URS online application, to request authority pursuant to 49 U.S.C. 13902, 13903, or 13904 to operate as a:

- (1) Motor carrier of property (not household goods), property (household goods) or passengers;
- (2) Broker of general commodities or household goods; or
- (3) Freight forwarder of general commodities or household goods.

(b) For purposes of this section, a “new applicant” is an entity applying for a USDOT number and if applicable, operating authority who does not at the time of application have an active registration or USDOT, Motor Carrier (MC), Mexico owned or controlled (MX) or Freight Forwarder (FF) number, and who has never had an active registration or USDOT, MC, MX, or FF number.

(c) Form MCSA–1 is the URS online application, and both the application and its instructions are available from the FMCSA Web site at <http://www.fmcsa.dot.gov/urs>.

■ 12. Add § 365.107T to read as follows:

#### **§ 365.107T Types of applications.**

(a) *Fitness applications.* Motor property applications and certain types of motor passenger applications require only the finding that the applicant is fit, willing and able to perform the involved operations and to comply with all applicable statutory and regulatory provisions. These applications can be opposed only on the grounds that applicant is not fit [*e.g.*, is not in

compliance with applicable financial responsibility and safety fitness requirements]. These applications are:

(1) Motor common and contract carrier of property (except household goods), Mexican motor property carriers that perform private carriage and transport exempt items, and motor contract carrier of passengers transportation.

(2) Motor carrier brokerage of general commodities (except household goods).

(3) Certain types of motor passenger applications as described in Form OP-1 (P).

(b) Motor passenger “public interest” applications as described in Form OP-1 (P).

(c) Intrastate motor passenger applications under 49 U.S.C. 13902(b)(3) as described in Form OP-1, Schedule B.

(d) *Motor common carrier of household goods applications, including Mexican carrier applicants.* These applications require a finding that:

(1) The applicant is fit, willing, and able to provide the involved transportation and to comply with all applicable statutory and regulatory provisions; and

(2) The service proposed will serve a useful public purpose, responsive to a public demand or need.

(e) *Motor contract carrier of household goods, household goods property broker, and freight forwarder applications.* These applications require a finding that:

(1) The applicant is fit, willing, and able to provide the involved transportation and to comply with all applicable statutory and regulatory provisions; and

(2) The transportation to be provided will be consistent with the public interest and the national transportation policy of 49 U.S.C. 13101.

(f) *Temporary authority (TA) for motor and water carriers.* These applications require a finding that there is or soon will be an immediate transportation need that cannot be met by existing carrier service.

(g) In view of the expedited time frames established in this part for processing requests for permanent authority, applications for TA will be entertained only in exceptional circumstances (*i.e.*, natural disasters or national emergencies) when evidence of immediate service need can be specifically documented in a narrative supplement appended to Form OP-1 for motor property carriers, Form OP-1MX for Mexican property carriers and, Form OP-1(P) for motor passenger carriers.

■ 13. Add § 365.109T to read as follows:

**§ 365.109T FMCSA review of the application.**

(a) FMCSA staff will review the application for correctness, completeness, and adequacy of the evidence (the *prima facie* case).

(1) Minor errors will be corrected without notification to the applicant.

(2) Materially incomplete applications will be rejected. Applications that are in substantial compliance with these rules may be accepted.

(3) All motor carrier applications will be reviewed for consistency with the FMCSA’s operational safety fitness policy. Applicants with “Unsatisfactory” safety fitness ratings from DOT will have their applications rejected.

(4) FMCSA staff will review completed applications that conform with the FMCSA’s safety fitness policy and that are accompanied by evidence of adequate financial responsibility.

(5) Financial responsibility is indicated by filing within 20 days from the date an application notice is published in the *FMCSA Register*:

(i) Form BMC-91 or 91X or BMC 82 surety bond—Bodily injury and property damage (motor property and passenger carriers; household goods freight forwarders that provide pickup or delivery service directly or by using a local delivery service under their control).

(ii) Form BMC-84—Surety bond or Form BMC-85—trust fund agreement (property brokers of general commodities and household goods).

(iii) Form BMC 34 or BMC 83 surety bond—Cargo liability (household goods motor carriers and household goods freight forwarders).

(6) Applicants also must submit Form BOC-3—designation of legal process agents—within 20 days from the date an application notice is published in the *FMCSA Register*.

(7) Applicants seeking to conduct operations for which tariffs are required may not commence such operations until tariffs are in effect.

(8) All applications must be completed in English.

(b) A summary of the application will be published as a preliminary grant of authority in the *FMCSA Register* to give notice to the public in case anyone wishes to oppose the application.

**§ 365.111 [SUSPENDED]**

■ 14. Suspend § 365.111.

■ 15. Add § 365.111T to read as follows:

**§ 365.111T Appeals to rejections of the application.**

(a) An applicant has the right to appeal rejection of the application. The

appeal must be filed at the FMCSA within 10 days of the date of the letter of rejection.

(b) If the appeal is successful and the filing is found to be proper, the application shall be deemed to have been properly filed as of the decision date of the appeal.

**§ 365.119 [SUSPENDED]**

■ 16. Suspend § 365.119.

■ 17. Add § 365.119T to read as follows:

**§ 365.119T Opposed applications.**

If the application is opposed, opposing parties are required to send a copy of their protest to the applicant.

**§§ 365.201 and 365.203 [SUSPENDED]**

■ 18. Suspend §§ 365.201 and 365.203.

■ 19. Add § 365.201T to read as follows:

**§ 365.201T Definitions.**

A person wishing to oppose a request for permanent authority files a protest. A person filing a valid protest becomes a *protestant*.

■ 20. Add § 365.203T to read as follows:

**§ 365.203T Time for filing.**

A protest shall be filed (received at the FMCSA) within 10 days after notice of the application appears in the *FMCSA Register*. A copy of the protest shall be sent to applicant’s representative at the same time. Failure timely to file a protest waives further participation in the proceeding.

**§ 365.301 [SUSPENDED]**

■ 21. Suspend § 365.301.

■ 22. Add § 365.301T to read as follows:

**§ 365.301T Applicable rules.**

Generally, all application proceedings are governed by the FMCSA’s Rules of Practice at part 386 of this chapter except as designated below.

**Subpart D—[SUSPENDED]**

■ 23. Suspend subpart D, consisting of §§ 365.401 through 365.413.

■ 24. Add new subpart D, consisting of §§ 365.401T through 365.413T, to read as follows:

**Subpart D—Transfer of Operating Rights Under 49 U.S.C. 10926**

Sec.

365.401T Scope of rules.

365.403T Definitions.

365.405T Applications.

365.407T Notice.

365.409T FMCSA action and criteria for approval.

365.411T Responsive pleadings.

365.413T Procedures for changing the name or business form of a motor carrier, freight forwarder, or property broker.

**§ 365.401T Scope of rules.**

These rules define the procedures that enable motor passenger and property carriers, property brokers, and household goods freight forwarders to obtain approval from the FMCSA to merge, transfer, or lease their operating rights in financial transactions not subject to 49 U.S.C. 11343. Transactions covered by these rules are governed by 49 U.S.C. 10321 and 10926. The filing fee is set forth at 49 CFR 360.3T(f)(8).

**§ 365.403T Definitions.**

For the purposes of this part, the following definitions apply:

(a) *Transfer*. Transfers include all transactions (*i.e.*, the sale or lease of interstate operating rights,<sup>1</sup> or the merger of two or more carriers or a carrier into a noncarrier) subject to 49 U.S.C. 10926, as well as the sale of property brokers' licenses under 49 U.S.C. 10321.

<sup>1</sup> The execution of a chattel mortgage, deed of trust, or other similar document does not constitute a transfer or require the FMCSA's approval. However, a foreclosure for the purpose of transferring an operating right to satisfy a judgment or claim against the record holder may not be effected without approval of the FMCSA.

(b) *Operating rights*. Operating rights include:

(1) Certificates and permits issued to motor carriers;

(2) Permits issued to freight forwarders;

(3) Licenses issued to property brokers; and

(4) Certificates of Registration issued to motor carriers. The term also includes authority held by virtue of the gateway elimination regulations published in the **Federal Register** as letter-notices.

(c) *Certificate of registration*. The evidence of a motor carrier's right to engage in interstate or foreign commerce within a single State is established by a corresponding State certificate.

(d) *Person*. An individual, partnership, corporation, company, association, or other form of business, or a trustee, receiver, assignee, or personal representative of any of these.

(e) *Record holder*. The person shown on the records of the FMCSA as the legal owner of the operating rights.

(f) *Control*. A relationship between persons that includes actual control, legal control, and the power to exercise control, through or by common directors, officers, stockholders, a voting trust, a holding or investment company, or any other means.

(g) *Category 1 transfers*. Transactions in which the person to whom the operating rights would be transferred is

not an FMCSA carrier and is not affiliated with any FMCSA carrier.

(h) *Category 2 transfers*. Transactions in which the person to whom the operating rights would be transferred is an FMCSA carrier and/or is affiliated with an FMCSA carrier.

**§ 365.405T Applications.**

(a) *Procedural requirements*. (1) At least 10 days before consummation, an original and two copies of a properly completed Form OP-FC-1 and any attachments (see paragraph (b)(1)(viii) of this section) must be filed with the Federal Motor Carrier Safety Administration, Office of Registration and Safety Information (MC-RS), 1200 New Jersey Ave. SE., Washington, DC 20590-0001.

(2) At any time after the expiration of the 10-day waiting period, applicants may consummate the transaction, subject to the subsequent approval of the application by the FMCSA, as described below. The transferee may commence operations under the rights acquired from the transferor upon its compliance with the FMCSA's regulations governing insurance, and process agents. See 49 CFR parts 387, subpart C, and 366, respectively. In the alternative, applicants may wait until the FMCSA has issued a decision on their application before transferring the operating rights. If the transferee wants the transferor's operating authority to be reissued in its name, it should furnish the FMCSA with a statement executed by both transferor and transferee indicating that the transaction has been consummated. Authority will not be reissued until after the FMCSA has approved the transaction.

(b) *Information required*. (1) In category 1 and category 2 transfers, applicants must furnish the following information:

(i) Full name, address, and signatures of the transferee and transferor.

(ii) A copy of the transferor's operating authority involved in the transfer proceeding.

(iii) A short summary of the essential terms of the transaction.

(iv) If relevant, the status of proceedings for the transfer of State certificate(s) corresponding to the Certificates of Registration being transferred.

(v) A statement as to whether the transfer will or will not significantly affect the quality of the human environment.

(vi) Certification by transferor and transferee of their current respective safety ratings by the United States Department of Transportation (*i.e.*,

satisfactory, conditional, unsatisfactory, or unrated).

(vii) Certification by the transferee that it has sufficient insurance coverage under 49 U.S.C. 13906 for the service it intends to provide.

(viii) Information to demonstrate that the proposed transaction is consistent with the national transportation policy and satisfies the criteria for approval set forth at § 365.409T. (Such information may be appended to the application form and, if provided, would be embraced by the oath and verification contained on that form.)

(ix) If motor carrier operating rights are being transferred, certification by the transferee that it is not domiciled in Mexico nor owned or controlled by persons of that country.

(2) Category 2 applicants must also submit the following additional information:

(i) Name(s) of the carrier(s), if any, with which the transferee is affiliated.

(ii) Aggregate revenues of the transferor, transferee, and their carrier affiliates from interstate transportation sources for a 1-year period ending not earlier than 6 months before the date of the agreement of the parties concerning the transaction. If revenues exceed \$2 million, the transfer may be subject to 49 U.S.C. 14303 rather than these rules.

**§ 365.407T Notice.**

The FMCSA will give notice of approved transfer applications through publication in the *FMCSA Register*.

**§ 365.409T FMCSA action and criteria for approval.**

A transfer will be approved under this section if:

(a) The transaction is not subject to 49 U.S.C. 14303; and

(b) The transaction is consistent with the public interest; however,

(c) If the transferor or transferee has an "Unsatisfactory" safety fitness rating from DOT, the transfer may be denied. If an application is denied, the FMCSA will set forth the basis for its action in a decision or letter notice. If parties with "Unsatisfactory" safety fitness ratings consummate a transaction pursuant to the 10-day rule at § 365.405T prior to the notification of FMCSA action, they do so at their own risk and subject to any conditions we may impose subsequently. Transactions that have been consummated but later are denied by the FMCSA are null and void and must be rescinded. Similarly, if applications contain false or misleading information, they are void *ab initio*.

**§ 365.411T Responsive pleadings.**

(a) Protests must be filed within 20 days after the date of publication of an

approved transfer application in the *FMCSA Register*. Protests received prior to the notice will be rejected. Applicants may respond within 20 days after the due date of protests. Petitions for reconsideration of decisions denying applications must be filed within 20 days after the date of service of such decisions.

(b) Protests and petitions for reconsideration must be filed with the Federal Motor Carrier Safety Administration, Office of Registration and Safety Information (MC-RS), 1200 New Jersey Ave. SE., Washington, DC 20590-0001, and be served on appropriate parties.

**§ 365.413T Procedures for changing the name or business form of a motor carrier, freight forwarder, or property broker.**

(a) *Scope*. These procedures apply in the following circumstances:

(1) A change in the form of a business, such as the incorporation of a partnership or sole proprietorship;

(2) A change in the legal name of a corporation or partnership or change in the trade name or assumed name of any entity;

(3) A transfer of operating rights from a deceased or incapacitated spouse to the other spouse;

(4) A reincorporation and merger for the purpose of effecting a name change;

(5) An amalgamation or consolidation of a carrier and a noncarrier into a new carrier having a different name from either of the predecessor entities; and

(6) A change in the State of incorporation accomplished by dissolving the corporation in one State and reincorporating in another State.

(b) *Procedures*. To accomplish these changes, a letter or signed copy of form MCSA-5889, "Motor Carrier Records Change Form," OMB No. 2126-0060, must be submitted to the Federal Motor Carrier Safety Administration. It must be submitted in one of the following three ways.

(1) Scanned and submitted via the web form at <https://www.fmcsa.dot.gov/ask>;

(2) Faxed to (202-366-3477); or

(3) Mailed to the Federal Motor Carrier Safety Administration, Office of Registration and Safety Information (MC-RS), 1200 New Jersey Ave. SE., Washington, DC 20590-0001. The envelope should be marked "NAME CHANGE".

(c) The registrant must provide:

(1) The docket number(s) and name of the carrier, freight forwarder, or property broker requesting the change;

(2) A copy of the articles of incorporation and the State certificate reflecting the incorporation;

(3) The name(s) of the owner(s) of the stock and the distribution of the shares;

(4) The names of the officers and directors of the corporation; and

(5) A statement that there is no change in the ownership, management, or control of the business. When this procedure is being used to transfer operating rights from a deceased or incapacitated spouse to the other spouse, documentation that the other spouse has the legal right to effect such change must be included with the request. The fee for filing a name change request is in § 360.3T(f) of this chapter.

**§§ 365.507 and 365.509 [SUSPENDED]**

■ 25. Suspend §§ 365.507 and 365.509.

■ 26. Add § 365.507T to read as follows:

**§ 365.507T FMCSA action on the application.**

(a) The FMCSA will review and act on each application submitted under this subpart in accordance with the procedures set out in this part.

(b) The FMCSA will validate the accuracy of information and certifications provided in the application by checking data maintained in databases of the governments of Mexico and the United States.

(c) *Pre-authorization safety audit*.

Every Mexico-domiciled carrier that applies under this part must satisfactorily complete an FMCSA-administered safety audit before FMCSA will grant provisional operating authority to operate in the United States. The safety audit is a review by the FMCSA of the carrier's written procedures and records to validate the accuracy of information and certifications provided in the application and determine whether the carrier has established or exercises the basic safety management controls necessary to ensure safe operations. The FMCSA will evaluate the results of the safety audit using the criteria in appendix A to this subpart.

(d) If a carrier successfully completes the pre-authorization safety audit and the FMCSA approves its application submitted under this subpart, FMCSA will publish a summary of the application as a preliminary grant of authority in the *FMCSA Register* to give notice to the public in case anyone wishes to oppose the application, as required in § 365.109T(b).

(e) If the FMCSA grants provisional operating authority to the applicant, it will assign a distinctive USDOT Number that identifies the motor carrier as authorized to operate beyond the municipalities in the United States on the U.S.-Mexico international border

and beyond the commercial zones of such municipalities. In order to operate in the United States, a Mexico-domiciled motor carrier with provisional operating authority must:

(1) Have its surety or insurance provider file proof of financial responsibility in the form of certificates of insurance, surety bonds, and endorsements, as required by § 387.301T of this subchapter;

(2) File a hard copy of, or have its process agent(s) electronically submit, Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders, as required by part 366 of this subchapter; and

(3) Comply with all provisions of the safety monitoring system in subpart B of part 385 of this subchapter, including successfully passing CVSA Level I inspections at least every 90 days and having decals affixed to each commercial motor vehicle operated in the United States as required by § 385.103(c) of this subchapter.

(f) The FMCSA may grant permanent operating authority to a Mexico-domiciled carrier no earlier than 18 months after the date that provisional operating authority is granted and only after successful completion to the satisfaction of the FMCSA of the safety monitoring system for Mexico-domiciled carriers set out in subpart B of part 385 of this subchapter. Successful completion includes obtaining a satisfactory safety rating as the result of a compliance review.

■ 26. Add § 365.509T to read as follows:

**§ 365.509T Requirement to notify FMCSA of change in applicant information.**

(a) A motor carrier subject to this subpart must notify the FMCSA of any changes or corrections to the information in parts I, IA or II submitted on the Form OP-1(MX) or the Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders during the application process or after having been granted provisional operating authority. The carrier must notify the FMCSA in writing within 45 days of the change or correction.

(b) If a carrier fails to comply with paragraph (a) of this section, the FMCSA may suspend or revoke its operating authority until it meets those requirements.

**PART 366—DESIGNATION OF PROCESS AGENT**

■ 27. The authority citation for part 366 is revised to read as follows:

**Authority:** 49 U.S.C. 502, 503, 13303, 13304 and 13908; and 49 CFR 1.87.

**§§ 366.1 through 366.6 [SUSPENDED]**

- 28. Suspend §§ 366.1 through 366.6.
- 29. Add §§ 366.1T through 366.6T to read as follows:

Sec.

- 366.1T Applicability.
- 366.2T Form of designation.
- 366.3T Eligible persons.
- 366.4T Required States.
- 366.5T Blanket designations.
- 366.6T Cancellation or change.

**§ 366.1T Applicability.**

These rules, relating to the filing of designations of persons upon whom court process may be served, govern motor carriers and brokers and, as of the moment of succession, their fiduciaries (as defined at 49 CFR 387.319(a)).

**§ 366.2T Form of designation.**

Designations shall be made on Form BOC-3, *Designation of Agent for Service of Process*. Only one completed current form may be on file. It must include all States for which agent designations are required. One copy must be retained by the carrier or broker at its principal place of business.

**§ 366.3T Eligible persons.**

All persons (as defined at 49 U.S.C. 13102(18)) designated as process agents must reside in or maintain an office in the State for which they are designated. If a State official is designated, evidence of his or her willingness to accept service of process must be furnished.

**§ 366.4T Required States.**

(a) *Motor carriers*. Every motor carrier (of property or passengers) shall make a designation for each State in which it is authorized to operate and for each State traversed during such operations. Every motor carrier (including private carriers) operating in the United States in the course of transportation between points in a foreign country shall file a designation for each State traversed.

(b) *Brokers*. Every broker shall make a designation for each State in which its offices are located or in which contracts will be written.

**§ 366.5T Blanket designations.**

Where an association or corporation has filed with the FMCSA a list of process agents for each State, motor carriers may make the required designations by using the following statement:

Those persons named in the list of process agents on file with the Federal Motor Carrier Safety Administration by \_\_\_\_\_ (Name of association or corporation) and any subsequently filed revisions thereof, for the States in which this carrier is or may be authorized to

operate, including States traversed during such operations, except those States for which individual designations are named.

**§ 366.6T Cancellation or change.**

A designation may be canceled or changed only by a new designation except that, where a carrier or broker ceases to be subject to § 366.4T in whole or in part for 1 year, designation is no longer required and may be canceled without making another designation.

**PART 368—APPLICATION FOR A CERTIFICATE OF REGISTRATION TO OPERATE IN MUNICIPALITIES IN THE UNITED STATES ON THE UNITED STATES-MEXICO INTERNATIONAL BORDER OR WITHIN THE COMMERCIAL ZONES OF SUCH MUNICIPALITIES**

- 30. The authority citation for part 368 is revised to read as follows:

**Authority:** 49 U.S.C. 13301, 13902 and 13908; Pub. L. 106-159, 113 Stat. 1748; and 49 CFR 1.87.

- 31. Add § 368.3-1T to read as follows:

**§ 368.3-1T Starting the application process: URS online application.**

(a) Notwithstanding any other provision of this part, new applicants as defined in paragraph (b) of this section must apply for a USDOT number and operating authority by electronically filing Form MCSA-1, the URS online application (available at <http://www.fmcsa.dot.gov/urs>) to request authority pursuant to 49 U.S.C. 13902 to provide interstate transportation in municipalities in the United States on the United States-Mexico international border or within the commercial zones of such municipalities as defined in 49 U.S.C. 13902(c)(4)(A).

(b) For purposes of this section, a “new applicant” is an citizen of Mexico or a motor carrier owned or controlled by a citizen of Mexico, applying for a USDOT number and operating authority who does not at the time of application have an active registration or USDOT, Motor Carrier (MC), Mexico owned or controlled (MX) or Freight Forwarder (FF) number, and who has never had an active registration or USDOT, MC, MX, or FF number.

(c) Form MCSA-1, is the URS online application, and both the application and its instructions are available from the FMCSA Web site at <http://www.fmcsa.dot.gov/urs>.

**§§ 368.3 and 368.4 [SUSPENDED]**

- 32. Suspend §§ 368.3 and 368.4.
- 33. Add § 368.3T to read as follows:

**§ 368.3T Applying for a certificate of registration.**

(a) If you wish to obtain a certificate of registration under this part, you must submit an application that includes the following:

(1) Form OP-2—Application for Mexican Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers Under 49 U.S.C. 13902;

(2) Form MCS-150—Motor Carrier Identification Report; and

(3) A notification of the means used to designate process agents, either by submission in the application package of Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders or a letter stating that the applicant will use a process agent service that will submit the Form BOC-3 electronically.

(b) The FMCSA will only process your application for a Certificate of Registration if it meets the following conditions:

(1) The application must be completed in English;

(2) The information supplied must be accurate and complete in accordance with the instructions to the Form OP-2, Form MCS-150 and Form BOC-3;

(3) The application must include all the required supporting documents and applicable certifications set forth in the instructions to the Form OP-2, Form MCS-150 and Form BOC-3;

(4) The application must include the filing fee payable to the FMCSA in the amount set forth in 49 CFR 360.3T(f)(1); and

(5) The application must be signed by the applicant.

(c) If you fail to furnish the complete application as described under paragraph (b) of this section your application may be rejected.

(d) If you submit false information under this section, you will be subject to applicable Federal penalties.

(e) You must submit the application to the address provided in the instructions to the Form OP-2.

(f) You may obtain the application described in paragraph (a) of this section from any FMCSA Division Office or download it from the FMCSA Web site at: <http://www.fmcsa.dot.gov/factsfigs/formspubs.htm>.

- 34. Add § 368.4T to read as follows:

**§ 368.4T Requirement to notify FMCSA of change in applicant information.**

(a) You must notify the FMCSA of any changes or corrections to the information in Parts I, IA or II submitted on the Form OP-2 or the Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders during

the application process or while you have a Certificate of Registration. You must notify the FMCSA in writing within 45 days of the change or correction.

(b) If you fail to comply with paragraph (a) of this section, the FMCSA may suspend or revoke the Certificate of Registration until you meet those requirements.

#### § 368.8 [SUSPENDED]

- 35. Suspend § 368.8.
- 36. Add § 368.8T to read as follows:

#### § 368.8T Appeals.

An applicant has the right to appeal denial of the application. The appeal must be in writing and specify in detail why the agency's decision to deny the application was wrong. The appeal must be filed with the Director, Office of Data Analysis and Information Systems within 20 days of the date of the letter denying the application. The decision of the Director will be the final agency order.

### PART 385—SAFETY FITNESS PROCEDURES

- 37. The authority citation for part 385 is revised to read as follows:

**Authority:** 49 U.S.C. 113, 504, 521(b), 5105(e), 5109, 5113, 13901–13905, 13908, 31136, 31144, 31148, 31151, and 31502; Sec. 350 of Pub. L. 107–87; and 49 CFR 1.87.

#### §§ 385.301 through 385.305 [SUSPENDED]

- 38. Suspend §§ 385.301 through 385.305.
- 39. Add § 385.301T to read as follows:

#### § 385.301T What is a motor carrier required to do before beginning interstate operations?

(a) Before a motor carrier of property or passengers begins interstate operations, it must register with the FMCSA and receive a USDOT number. In addition, for-hire motor carriers must obtain operating authority from FMCSA following the registration procedures described in 49 CFR part 365, unless providing transportation exempt from 49 CFR part 365 registration requirements.

(b) This subpart applies to motor carriers domiciled in the United States and Canada.

(c) A Mexico-domiciled motor carrier of property or passengers must register with the FMCSA by following the registration procedures described in 49 CFR part 365 or 368, as appropriate. The regulations in this subpart do not apply to Mexico-domiciled carriers.

- 40. Add § 385.303T to read as follows:

#### § 385.303T How does a motor carrier register with the FMCSA?

A motor carrier may contact the FMCSA by internet ([www.fmcsa.dot.gov](http://www.fmcsa.dot.gov)); or Washington, DC headquarters by mail at, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590–0001; fax 202–366–3477; or telephone 1–800–832–5660, and request the application materials for a new entrant motor carrier. Forms can also be downloaded from <https://www.fmcsa.dot.gov/registration/registration-forms>. A motor carrier which does not already have a USDOT number must apply online via the Unified Registration System (URS) at [www.fmcsa.dot.gov/urs](http://www.fmcsa.dot.gov/urs).

- 41. Add § 385.305T to read as follows:

#### § 385.305T What happens after the FMCSA receives a request for new entrant registration?

(a) The requester for new entrant registration will be directed to the FMCSA Internet Web site ([www.fmcsa.dot.gov](http://www.fmcsa.dot.gov)) to secure and/or complete the application package online.

(b) The application package will contain the following:

(1) Educational and technical assistance material regarding the requirements of the FMCSRs and HMRs, if applicable.

(2) The Form MCS–150, The Motor Carrier Identification Report.

(3) Application forms to obtain operating authority under 49 CFR part 365, as appropriate.

(c) Upon completion of the application forms, the new entrant will be issued a USDOT number.

(d) For-hire motor carriers, unless providing transportation exempt from 49 CFR part 365 registration requirements, must also comply with the procedures established in 49 CFR part 365 to obtain operating authority before operating in interstate commerce.

#### § 385.329 [SUSPENDED]

- 42. Suspend § 385.329.
- 43. Add § 385.329T to read as follows:

#### § 385.329T May a new entrant that has had its USDOT new entrant registration revoked and its operations placed out of service reapply?

(a) A new entrant whose USDOT new entrant registration has been revoked, and whose operations have been placed out of service by FMCSA, may reapply for new entrant registration no sooner than 30 days after the date of revocation.

(b) If the USDOT new entrant registration was revoked because of a failed safety audit, the new entrant must do all of the following:

(1) Submit an updated MCS–150.  
 (2) Submit evidence that it has corrected the deficiencies that resulted in revocation of its registration and will otherwise ensure that it will have basic safety management controls in effect.

(3) Begin the 18-month new entrant monitoring cycle again as of the date the re-filed application is approved.

(c) If the USDOT new entrant registration was revoked because FMCSA found that the new entrant had failed to submit to a safety audit, it must do all of the following:

(1) Submit an updated MCS–150.  
 (2) Begin the 18-month new entrant monitoring cycle again as of the date the re-filed application is approved.  
 (3) Submit to a safety audit.

(d) If the new entrant is a for-hire carrier subject to the registration provisions under 49 U.S.C. 13901 and also has had its operating authority revoked, it must re-apply for operating authority as set forth in part 365 of this chapter.

#### § 385.405 [SUSPENDED]

- 44. Suspend § 385.405.
- 45. Add § 385.405T to read as follows:

#### § 385.405T How does a motor carrier apply for a safety permit?

(a) *Application form(s)*. (1) To apply for a new safety permit or renewal of the safety permit, a motor carrier must complete and submit Form MCS–150B, Combined Motor Carrier Identification Report and HM Permit Application.

(2) The Form MCS–150B will also satisfy the requirements for obtaining and renewing a USDOT Number; there is no need to complete Form MCS–150, Motor Carrier Identification Report.

(b) *Where to get forms and instructions*. The forms listed in paragraph (a) of this section, and instructions for completing the forms, may be obtained on the Internet at <http://www.fmcsa.dot.gov>, or by contacting FMCSA at Federal Motor Carrier Safety Administration, Office of Information Technology (MC–RI), 1200 New Jersey Ave. SE., Washington, DC 20590–0001, Telephone: 1–800–832–5660.

(c) *Registration with the Pipeline and Hazardous Materials Safety Administration (PHMSA)*. The motor carrier must be registered with PHMSA in accordance with part 107, subpart G, of this title.

(d) *Updating information on Form MCS–150B*. A motor carrier holding a safety permit must report to FMCSA any change in the information on its Form MCS–150B within 30 days of the change. The motor carrier must use Form MCS–150B to report the new



information (contact information in paragraph (b) of this section).

**§ 385.409 [SUSPENDED]**

■ 46. Suspend § 385.409.

■ 47. Add § 385.409T to read as follows:

**§ 385.409T When may a temporary safety permit be issued to a motor carrier?**

(a) *Temporary safety permit.* If a motor carrier does not meet the criteria in § 385.407(a), FMCSA may issue it a temporary safety permit. To obtain a temporary safety permit a motor carrier must certify on Form MCS-150B that it is operating in full compliance with the HMRs; with the FMCSRs, and/or comparable State regulations, whichever is applicable; and with the minimum financial responsibility requirements in part 387 of this chapter or in State regulations, whichever is applicable.

(b) FMCSA will not issue a temporary safety permit to a motor carrier that:

(1) Does not certify that it has a satisfactory security program as required in § 385.407(b);

(2) Has a crash rate in the top 30 percent of the national average as indicated in the FMCSA's Motor Carrier Management Information System (MCMIS); or

(3) Has a driver, vehicle, hazardous materials, or total out-of-service rate in the top 30 percent of the national average as indicated in the MCMIS.

(c) A temporary safety permit shall be valid for 180 days after the date of issuance or until the motor carrier is assigned a new safety rating, whichever occurs first.

(1) A motor carrier that receives a Satisfactory safety rating will be issued a safety permit (see § 385.421T).

(2) A motor carrier that receives a less than Satisfactory safety rating is ineligible for a safety permit and will be subject to revocation of its temporary safety permit.

(d) If a motor carrier has not received a safety rating within the 180-day time period, FMCSA will extend the effective date of the temporary safety permit for an additional 60 days, provided the motor carrier demonstrates that it is continuing to operate in full compliance with the FMCSRs and HMRs.

**§§ 385.419 and 385.421 [SUSPENDED]**

■ 48. Suspend §§ 385.419 and 385.421.

■ 49. Add § 385.419T to read as follows:

**§ 385.419T How long is a safety permit effective?**

Unless suspended or revoked, a safety permit (other than a temporary safety permit) is effective for two years, except that:

(a) A safety permit will be subject to revocation if a motor carrier fails to

submit a renewal application (Form MCS-150B) in accordance with the schedule set forth for filing Form MCS-150 in § 390.19T(a) of this chapter; and

(b) An existing safety permit will remain in effect pending FMCSA's processing of an application for renewal if a motor carrier submits the required application (Form MS-150B) in accordance with the schedule set forth in § 390.19T(a)(2) and (3) of this chapter.

■ 50. Add § 385.421T to read as follows:

**§ 385.421T Under what circumstances will a safety permit be subject to revocation or suspension by FMCSA?**

(a) *Grounds.* A safety permit will be subject to revocation or suspension by FMCSA for the following reasons:

(1) A motor carrier fails to submit a renewal application (Form MCS-150B) in accordance with the schedule set forth in § 390.19T(a)(2) and (3) of this chapter;

(2) A motor carrier provides any false or misleading information on its application (Form MCS-150B) or as part of updated information it is providing on Form MCS-150B (see § 385.405T(d)).

(3) A motor carrier is issued a final safety rating that is less than Satisfactory;

(4) A motor carrier fails to maintain a satisfactory security plan as set forth in § 385.407(b);

(5) A motor carrier fails to comply with applicable requirements in the FMCSRs, the HMRs, or compatible State requirements governing the transportation of hazardous materials, in a manner showing that the motor carrier is not fit to transport the hazardous materials listed in § 385.403;

(6) A motor carrier fails to comply with an out-of-service order;

(7) A motor carrier fails to comply with any other order issued under the FMCSRs, the HMRs, or compatible State requirements governing the transportation of hazardous materials, in a manner showing that the motor carrier is not fit to transport the hazardous materials listed in § 385.403;

(8) A motor carrier fails to maintain the minimum financial responsibility required by § 387.9 of this chapter or an applicable State requirement;

(9) A motor carrier fails to maintain current hazardous materials registration with the Pipeline and Hazardous Materials Safety Administration; or

(10) A motor carrier loses its operating rights or has its registration suspended in accordance with § 386.83 or § 386.84 of this chapter for failure to pay a civil penalty or abide by a payment plan.

(b) *Determining whether a safety permit is revoked or suspended.* A

motor carrier's safety permit will be suspended the first time any of the conditions specified in paragraph (a) of this section are found to apply to the motor carrier. A motor carrier's safety permit will be revoked if any of the conditions specified in paragraph (a) of this section are found to apply to the motor carrier and the carrier's safety permit has been suspended in the past for any of the reasons specified in paragraph (a) of this section.

(c) *Effective date of suspension or revocation.* A suspension or revocation of a safety permit is effective:

(1) Immediately after FMCSA determines that an imminent hazard exists, after FMCSA issues a final safety rating that is less than Satisfactory, or after a motor carrier loses its operating rights or has its registration suspended for failure to pay a civil penalty or abide by a payment plan;

(2) Thirty (30) days after service of a written notification that FMCSA proposes to suspend or revoke a safety permit, if the motor carrier does not submit a written request for administrative review within that time period; or

(3) As specified in § 385.423(c), when the motor carrier submits a written request for administrative review of FMCSA's proposal to suspend or revoke a safety permit.

(4) A motor carrier whose safety permit has been revoked will not be issued a replacement safety permit or temporary safety permit for 365 days from the time of revocation.

**§ 385.603 [SUSPENDED]**

■ 51. Suspend § 385.603.

■ 52. Add § 385.603T to read as follows:

**§ 385.603T Application.**

(a) Each applicant applying under this subpart must submit an application that consists of:

(1) Form OP-1(NNA)—Application for U.S. Department of Transportation (USDOT) Registration by Non-North America-Domiciled Motor Carriers;

(2) Form MCS-150—Motor Carrier Identification Report; and

(3) A notification of the means used to designate process agents, either by submission in the application package of Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders or a letter stating that the applicant will use a process agent service that will submit the Form BOC-3 electronically.

(b) FMCSA will only process an application if it meets the following conditions:

(1) The application must be completed in English;

(2) The information supplied must be accurate, complete, and include all required supporting documents and applicable certifications in accordance with the instructions to Form OP-1(NNA), Form MCS-150 and Form BOC-3;

(3) The application must include the filing fee payable to the FMCSA in the amount set forth at 49 CFR 360.3T(f)(1); and

(4) The application must be signed by the applicant.

(c) An applicant must submit the application to the address provided in Form OP-1(NNA).

(d) An applicant may obtain the application forms from any FMCSA Division Office or download them from the FMCSA Web site at: <http://www.fmcsa.dot.gov/forms/forms.htm>.

**§§ 385.607 and 385.609 [SUSPENDED]**

■ 53. Suspend §§ 385.607 and 385.609.

■ 54. Add § 385.607T to read as follows:

**§ 385.607T FMCSA action on the application.**

(a) FMCSA will review and act on each application submitted under this subpart in accordance with the procedures set out in this part.

(b) FMCSA will validate the accuracy of information and certifications provided in the application by checking, to the extent available, data maintained in databases of the governments of the country where the carrier's principal place of business is located and the United States.

(c) Pre-authorization safety audit. Every non-North America-domiciled motor carrier that applies under this part must satisfactorily complete an FMCSA-administered safety audit before FMCSA will grant new entrant registration to operate in the United States. The safety audit is a review by FMCSA of the carrier's written procedures and records to validate the accuracy of information and certifications provided in the application and determine whether the carrier has established or exercises the basic safety management controls necessary to ensure safe operations. FMCSA will evaluate the results of the safety audit using the criteria in the appendix to this subpart.

(d) An application of a non-North America-domiciled motor carrier requesting for-hire operating authority under part 365 of this subchapter may be protested under § 365.109T(b). Such a carrier will be granted new entrant registration after successful completion of the pre-authorization safety audit and the expiration of the protest period, provided the application is not

protested. If a protest to the application is filed with FMCSA, new entrant registration will be granted only if FMCSA denies or rejects the protest.

(e) If FMCSA grants new entrant registration to the applicant, it will assign a distinctive USDOT Number that identifies the motor carrier as authorized to operate in the United States. In order to initiate operations in the United States, a non-North America-domiciled motor carrier with new entrant registration must:

(1) Have its surety or insurance provider file proof of financial responsibility in the form of certificates of insurance, surety bonds, and endorsements, as required by §§ 387.7(e)(2), 387.31(e)(2), and 387.301T of this subchapter, as applicable; and

(2) File a hard copy of, or have its process agent(s) electronically submit, Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders, as required by part 366 of this subchapter.

(f) A non-North America-domiciled motor carrier must comply with all provisions of the safety monitoring system in subpart I of this part, including successfully passing North American Standard commercial motor vehicle inspections at least every 90 days and having safety decals affixed to each commercial motor vehicle operated in the United States as required by § 385.703(c).

(g) FMCSA may not re-designate a non-North America-domiciled carrier's registration from new entrant to permanent prior to 18 months after the date its USDOT Number is issued and subject to successful completion of the safety monitoring system for non-North America-domiciled carriers set out in subpart I of this part. Successful completion includes obtaining a Satisfactory safety rating as the result of a compliance review.

■ 55. Add § 385.609T to read as follows:

**§ 385.609T Requirement to notify FMCSA of change in applicant information.**

(a)(1) A motor carrier subject to this subpart must notify FMCSA of any changes or corrections to the information the Form BOC-3—Designation of Agents—Motor Carriers, Brokers and Freight Forwarders that occur during the application process or after having been granted new entrant registration.

(2) A motor carrier subject to this subpart must notify FMCSA of any changes or corrections to the information in Section I, IA or II of Form OP-1(NNA)—Application for U.S. Department of Transportation (USDOT)

Registration by Non-North America-Domiciled Motor Carriers that occurs during the application process or after having been granted new entrant registration.

(3) A motor carrier must notify FMCSA in writing within 45 days of the change or correction to information under paragraph (a)(1) or (2) of this section.

(b) If a motor carrier fails to comply with paragraph (a) of this section, FMCSA may suspend or revoke its new entrant registration until it meets those requirements.

**§ 385.713 [SUSPENDED]**

■ 56. Suspend § 385.713.

■ 57. Add § 385.713T to read as follows:

**§ 385.713T Reapplying for new entrant registration.**

(a) A non-North America-domiciled motor carrier whose provisional new entrant registration has been revoked may reapply for new entrant registration no sooner than 30 days after the date of revocation.

(b) If the provisional new entrant registration was revoked because the new entrant failed to receive a Satisfactory rating after undergoing a compliance review, the new entrant must do all of the following:

(1) Submit an updated MCS-150.

(2) Submit evidence that it has corrected the deficiencies that resulted in revocation of its registration and will otherwise ensure that it will have basic safety management controls in effect.

(3) Successfully complete a pre-authorization safety audit in accordance with § 385.607T(c).

(4) Begin the 18-month new entrant monitoring cycle again as of the date the re-filed application is approved.

(c) If the provisional new entrant registration was revoked because FMCSA found that the new entrant had failed to submit to a compliance review, it must do all of the following:

(1) Submit an updated MCS-150.

(2) Successfully complete a pre-authorization safety audit in accordance with § 385.607T(c).

(3) Begin the 18-month new entrant monitoring cycle again as of the date the re-filed application is approved.

(4) Submit to a compliance review upon request.

(d) If the new entrant is a for-hire carrier subject to the registration provisions under 49 U.S.C. 13901 and also has had its operating authority revoked, it must re-apply for operating authority as set forth in part 365 of this subchapter.

**PART 387—MINIMUM LEVELS OF FINANCIAL RESPONSIBILITY FOR MOTOR CARRIERS**

■ 58. The authority citation for part 387 is revised to read as follows:

**Authority:** 49 U.S.C. 13101, 13301, 13906, 13908, 14701, 31138, and 31139; and 49 CFR 1.87.

**§ 387.19 [SUSPENDED]**

■ 59. Suspend § 387.19.

**§ 387.33 [SUSPENDED]**

■ 60. Suspend § 387.33.

■ 61. Add § 387.33T to read as follows:

**§ 387.33T Financial responsibility, minimum levels.**

The minimum levels of financial responsibility referred to in § 387.31 are hereby prescribed as follows:

**Schedule of Limits**

*Public Liability*

For-hire motor carriers of passengers operating in interstate or foreign commerce.

Vehicle seating capacity	Effective dates	
	Nov. 19, 1983	Nov. 19, 1985
(1) Any vehicle with a seating capacity of 16 passengers or more .....	\$2,500,000	\$5,000,000
(2) Any vehicle with a seating capacity of 15 passengers or less <sup>1</sup> .....	750,000	1,500,000

<sup>1</sup> Except as provided in § 387.27(b).

**§ 387.43 [Suspended]**

■ 62. Suspend § 387.43.

**§§ 387.301 and 387.303 [Suspended]**

■ 63. Suspend §§ 387.301 and 387.303.

■ 64. Add § 387.301T to read as follows:

**§ 387.301T Surety bond, certificate of insurance, or other securities.**

(a) *Public liability.* (1) No common or contract carrier or foreign (Mexican) motor private carrier or foreign motor carrier transporting exempt commodities subject to Subtitle IV, part B, chapter 135 of title 49 of the U.S. Code shall engage in interstate or foreign commerce, and no certificate or permit shall be issued to such a carrier or remain in force unless and until there shall have been filed with and accepted by the FMCSA surety bonds, certificates of insurance, proof of qualifications as self-insurer, or other securities or agreements, in the amounts prescribed in § 387.303T, conditioned to pay any final judgment recovered against such motor carrier for bodily injuries to or the death of any person resulting from the negligent operation, maintenance or use of motor vehicles in transportation subject to Subtitle IV, part B, chapter

135 of title 49 of the U.S. Code, or for loss of or damage to property of others, or, in the case of motor carriers of property operating freight vehicles described in § 387.303T(b)(2), for environmental restoration.

(2) Motor Carriers of property which are subject to the conditions set forth in paragraph (a)(1) of this section and transport the commodities described in § 387.303T(b)(2), are required to obtain security in the minimum limits prescribed in § 387.303T(b)(2).

(b) *Household goods motor carriers-cargo insurance.* No household goods motor carrier subject to subtitle IV, part B, chapter 135 of title 49 of the U.S. Code shall engage in interstate or foreign commerce, nor shall any certificate be issued to such a household goods motor carrier or remain in force unless and until there shall have been filed with and accepted by the FMCSA, a surety bond, certificate of insurance, proof of qualifications as a self-insurer, or other securities or agreements in the amounts prescribed in § 387.303T, conditioned upon such carrier making compensation to individual shippers for all property belonging to individual shippers and coming into the possession

of such carrier in connection with its transportation service. The terms “household goods motor carrier” and “individual shipper” are defined in part 375 of this subchapter.

(c) *Continuing compliance required.* Such security as is accepted by the FMCSA in accordance with the requirements of section 13906 of title 49 of the U.S. Code, shall remain in effect at all times.

■ 65. Add § 387.303T to read as follows:

**§ 387.303T Security for the protection of the public: Minimum limits.**

(a) *Definitions.* (1) *Primary security* means public liability coverage provided by the insurance or surety company responsible for the first dollar of coverage.

(2) *Excess security* means public liability coverage above the primary security, or above any additional underlying security, up to and including the required minimum limits set forth in paragraph (b)(2) of this section.

(b)(1) Motor carriers subject to § 387.301T(a)(1) are required to have security for the required minimum limits as follows:

(i) *Small freight vehicles.*

Kind of equipment	Transportation provided	Minimum limits
Fleet including only vehicles under 10,001 pounds (4,536 kilograms) GVWR .....	Property (non-hazardous) .....	\$300,000

(ii) *Passenger carriers.*

**PASSENGER CARRIERS: KIND OF EQUIPMENT**

Vehicle seating capacity	Minimum limits
(A) Any vehicle with a seating capacity of 16 passengers or more (including the driver) .....	\$5,000,000
(B) Any vehicle designed or used to transport 15 passengers or less (including the driver) for compensation .....	1,500,000

(2) Motor carriers subject to § 387.301T(a)(2) are required to have

security for the required minimum limits as follows:

Kind of equipment	Commodity transported	Minimum limits
(i) Freight vehicles of 10,001 pounds (4,536 kilograms) or more GVWR.	Property (non-hazardous) .....	\$750,000
(ii) Freight vehicles of 10,001 (4,536 kilograms) pounds or more GVWR.	Hazardous substances, as defined in § 171.8 of this title, transported in cargo tanks, portable tanks, or hopper-type vehicles with capacities in excess of 3,500 water gallons, or in bulk explosives Division 1.1, 1.2 and 1.3 materials. Division 2.3, Hazard Zone A material; in bulk Division 2.1 or 2.2; or highway route controlled quantities of a Class 7 material, as defined in § 173.403 of this title.	5,000,000
(iii) Freight vehicles of 10,001 pounds (4,536 kilograms) or more GVWR.	Oil listed in § 172.101 of this title; hazardous waste, hazardous materials and hazardous substances defined in § 171.8 of this title and listed in § 172.101 of this title, but not mentioned in paragraph (b) or (d) of this section.	1,000,000
(iv) Freight vehicles under 10,001 pounds (4,536 kilograms) GVWR.	Any quantity of Division 1.1, 1.2, or 1.3 material; any quantity of a Division 2.3, Hazard Zone A, or Division 6.1, Packing Group I, Hazard Zone A material; or highway route controlled quantities of Class 7 material as defined in § 173.455 of this title.	5,000,000

(3) Motor carriers subject to the minimum limits governed by this section, which are also subject to Department of Transportation limits requirements, are at no time required to have security for more than the required minimum limits established by the Secretary of Transportation in the applicable provisions of this part.

(4) *Foreign motor carriers and foreign motor private carriers.* Foreign motor carriers and foreign motor private carriers (Mexican), subject to the requirements of 49 U.S.C. 13902(c) and 49 CFR part 368 regarding obtaining certificates of registration from the FMCSA, must meet our minimum financial responsibility requirements by obtaining insurance coverage, in the required amounts, for periods of 24 hours or longer, from insurance or surety companies, that meet the requirements of § 387.315. These carriers must have available for inspection, in each vehicle operating in the United States, copies of the following documents:

- (i) The certificate of registration;
- (ii) The required insurance endorsement (Form MCS-90); and
- (iii) An insurance identification card, binder, or other document issued by an authorized insurer which specifies both the effective date and the expiration date of the insurance coverage.

Notwithstanding the provisions of § 387.301T(a)(1), the filing of evidence of insurance is not required as a condition to the issuance of a certificate of registration. Further, the reference to continuous coverage at § 387.313T(a)(6) and the reference to cancellation notice at § 387.313T(d) are not applicable to these carriers.

(c) *Household goods motor carriers: Cargo liability.* Security required to compensate individual shippers for loss or damage to property belonging to them

and coming into the possession of household goods motor carriers in connection with their transportation service:

- (1) For loss of or damage to household goods carried on any one motor vehicle—\$5,000; and
- (2) For loss of or damage to or aggregate of losses or damages of or to household goods occurring at any one time and place—\$10,000.

**§ 387.313 [Suspended]**

- 66. Suspend § 387.313.
- 67. Add § 387.313T to read as follows:

**§ 387.313T Forms and procedures.**

(a) *Forms for endorsements, certificates of insurance and others—(1) In form prescribed.* Endorsements for policies of insurance and surety bonds, certificates of insurance, applications to qualify as a self-insurer, or for approval of other securities or agreements, and notices of cancellation must be in the form prescribed and approved by the FMCSA.

(2) *Aggregation of insurance.* (i) When insurance is provided by more than one insurer in order to aggregate security limits for carriers operating only freight vehicles under 10,000 pounds Gross Vehicle Weight Rating, as defined in § 387.303T(b)(1), a separate *Form BMC 90*, with the specific amounts of underlying and limits of coverage shown thereon or appended thereto, and *Form BMC 91X* certificate is required of each insurer.

**\*\*Note:** See Note for Rule 387.311. Also, it should be noted that DOT is considering prescribing adaptations of the *Form MCS 90* endorsement and the *Form MCS 82* surety bond for use by passenger carriers and Rules §§ 387.311 and 387.313T have been written sufficiently broad to provide for this contingency when new forms are prescribed by that Agency.

(ii) For aggregation of insurance for all other carriers to cover security limits under § 387.303T(b)(1) or (2), a separate Department of Transportation prescribed form endorsement and *Form BMC 91X* certificate is required of each insurer. When insurance is provided by more than one insurer to aggregate coverage for security limits under § 387.303T(c) a separate *Form BMC 32* endorsement and *Form BMC 34* certificate of insurance is required for each insurer.

(iii) For aggregation of insurance for foreign motor private carriers of nonhazardous commodities to cover security limits under § 387.303T(b)(4), a separate *Form BMC 90* with the specific amounts of underlying and limits of coverage shown thereon or appended thereto, or Department of Transportation prescribed form endorsement, and *Form BMC 91MX* certificate is required for each insurer.

(3) *Use of certificates and endorsements in BMC Series.* Form BMC 91 certificates of insurance will be filed with the FMCSA for the full security limits under § 387.303T(b)(1) or (2).

(i) *Form BMC 91X* certificate of insurance will be filed to represent full coverage or any level of aggregation for the security limits under § 387.303T(b)(1) or (2).

(ii) *Form BMC 90* endorsement will be used with each filing of *Form BMC 91* or *Form 91X* certificate with the FMCSA which certifies to coverage not governed by the requirements of the Department of Transportation. *Form BMC 32* endorsement and *Form BMC 34* certificate of insurance and *Form BMC 83* surety bonds are used for the limits of cargo liability under § 387.303T(c).

(iii) *Form BMC 91MX* certificate of insurance will be filed to represent any level of aggregation for the security limits under § 387.303T(b)(4).

(4) *Use of endorsements in MCS Series.* When Security limits certified under § 387.303T(b)(1) or (b)(2) involves coverage also required by the Department of Transportation a Form MCS endorsement prescribed by the Department of Transportation such as, and including, the Form MCS 90 endorsement is required.

(5) *Surety bonds.* When surety bonds are used rather than certificates of insurance, Form BMC 82 is required for the security limits under § 387.303T(b)(1) not subject to regulation by the Department of Transportation, and Form MCS 82, or any form of similar import prescribed by the Department of Transportation, is used for the security limits subject also to minimum coverage requirements of the Department of Transportation.

(6) *Surety bonds and certificates in effect continuously.* Surety bonds and certificates of insurance shall specify that coverage thereunder will remain in effect continuously until terminated as herein provided, except:

(i) When filed expressly to fill prior gaps or lapses in coverage or to cover grants of emergency temporary authority of unusually short duration and the filing clearly so indicates; or

(ii) In special or unusual circumstances, when special permission is obtained for filing certificates of insurance or surety bonds on terms meeting other particular needs of the situation.

(b) *Filing and copies.* Certificates of insurance, surety bonds, and notices of cancellation must be filed with the FMCSA in triplicate.

(c) *Name of insured.* Certificates of insurance and surety bonds shall be

issued in the full and correct name of the individual, partnership, corporation or other person to whom the certificate, permit, or license is, or is to be, issued. In the case of a partnership, all partners shall be named.

(d) *Cancellation notice.* Except as provided in paragraph (e) of this section, surety bonds, certificates of insurance and other securities or agreements shall not be cancelled or withdrawn until 30 days after written notice has been submitted to the FMCSA at its offices in Washington, DC, on the prescribed form (*Form BMC-35*, Notice of Cancellation Motor Carrier Policies of Insurance under 49 U.S.C. 13906, and *BMC-36*, Notice of Cancellation Motor Carrier and Broker Surety Bonds, as appropriate) by the insurance company, surety or sureties, motor carrier, broker or other party thereto, as the case may be, which period of thirty (30) days shall commence to run from the date such notice on the prescribed form is actually received by the FMCSA.

(e) *Termination by replacement.* Certificates of insurance or surety bonds which have been accepted by the FMCSA under these rules may be replaced by other certificates of insurance, surety bonds or other security, and the liability of the retiring insurer or surety under such certificates of insurance or surety bonds shall be considered as having terminated as of the effective date of the replacement certificate of insurance, surety bond or other security, provided the said replacement certificate, bond or other security is acceptable to the FMCSA under the rules and regulations in this part.

(f) *Termination of Forms BMC-32 and BMC-34 for motor carriers transporting property other than household goods.* Form *BMC-32* endorsements and Form *BMC-34* certificates of insurance issued to motor carriers transporting property other than household goods that have been accepted by the FMCSA under these rules will expire on March 21, 2011.

**§ 387.323 [Suspended]**

■ 68. Suspend § 387.323.

■ 69. Add § 387.323T to read as follows:

**§ 387.323T Electronic filing of surety bonds, trust fund agreements, certificates of insurance and cancellations.**

(a) Insurers may, at their option and in accordance with the requirements and procedures set forth in paragraphs (a) through (d) of this section, file forms BMC 34, BMC 35, BMC 36, BMC 82, BMC 83, BMC 84, BMC 85, BMC 91, and BMC 91X electronically, in lieu of using the prescribed printed forms.

(b) Each insurer must obtain authorization to file electronically by registering with the FMCSA. An individual account number and password for computer access will be issued to each registered insurer.

(c) Filings may be transmitted online via the Internet at: <http://fhwa-li.volpe.dot.gov> or via American Standard Code Information Interchange (ASCII). All ASCII transmission must be in fixed format, *i.e.*, all records must have the same number of fields and same length. The record layouts for ASCII electronic transactions are described in the following table:

**ELECTRONIC INSURANCE FILING TRANSACTIONS**

Field name	Number of positions	Description	Required F = filing C = cancel B = both	Start field	End field
Record type .....	1 Numeric .....	1 = Filing, 2 = Cancellation .....	B	1	1
Insurer number .....	8 Text .....	FMCSA Assigned Insurer Number (Home Office) With Suffix (Issuing Office), If Different, <i>e.g.</i> , 12345-01.	B	2	9
Filing type .....	1 Numeric .....	1 = BI&PD, 2 = Cargo, 3 = Bond, 4 = Trust Fund.	B	10	10
FMCSA docket number	8 Text .....	FMCSA Assigned MC or FF Number, <i>e.g.</i> , MC000045.	B	11	18
Insured legal name .....	120 Text .....	Legal Name .....	B	19	138
Insured d/b/a name .....	60 Text .....	Doing Business As Name If Different From Legal Name.	B	139	198
Insured address .....	35 Text .....	Either street or mailing address .....	B	199	233
Insured city .....	30 Text .....	.....	B	234	263
Insured state .....	2 Text .....	.....	B	264	265
Insured zip code .....	9 Numeric .....	(Do not include dash if using 9 digit code) .....	B	266	274
Insured country .....	2 Text .....	(Will default to U.S.) .....	B	275	276
Form code .....	10 Text .....	BMC-91, BMC-91X, BMC-34, BMC-35, etc ...	B	277	286

## ELECTRONIC INSURANCE FILING TRANSACTIONS—Continued

Field name	Number of positions	Description	Required F = filing C = cancel B = both	Start field	End field
Full, primary or excess coverage.	1 Text .....	If BMC-91X, P or E = indicator of primary or excess policy; 1 = Full under § 387.303T(b)(1); 2 = Full under § 387.303T(b)(2).	F	287	287
Limit of liability .....	5 Numeric .....	\$ in Thousands .....	F	288	292
Underlying limit of liability.	5 Numeric .....	\$ in Thousands (will default to \$000 if Primary)	F	293	297
Effective date .....	8 Text .....	MM/DD/YY Format for both Filing or Cancellation.	B	298	305
Policy number .....	25 Text .....	Surety companies may enter bond number .....	B	306	330

(d) All registered insurers agree to furnish upon request to the FMCSA a duplicate original of any policy (or policies) and all endorsements, surety bond, trust fund agreement, or other filing.

#### § 387.403 [Suspended]

■ 70. Suspend § 387.403.

■ 71. Add § 387.403T to read as follows:

#### § 387.403T General requirements.

(a) *Cargo*. A household goods freight forwarder may not operate until it has filed with FMCSA an appropriate surety bond, certificate of insurance, qualifications as a self-insurer, or other securities or agreements, in the amounts prescribed in § 387.405, for loss of or damage to household goods.

(b) *Public liability*. A HHGFF may not perform transfer, collection, and delivery service until it has filed with the FMCSA an appropriate surety bond, certificate of insurance, qualifications as a self-insurer, or other securities or agreements, in the amounts prescribed at § 387.405, conditioned to pay any final judgment recovered against such HHGFF for bodily injury to or the death of any person, or loss of or damage to property (except cargo) of others, or, in the case of freight vehicles described at § 387.303T(b)(2), for environmental restoration, resulting from the negligent operation, maintenance, or use of motor vehicles operated by or under its control in performing such service.

(c) *Surety bond or trust fund*. A freight forwarder must have a surety bond or trust fund in effect. The FMCSA will not issue a freight forwarder license until a surety bond or trust fund for the full limit of liability prescribed in § 387.405 is in effect. The freight forwarder license shall remain valid or effective only as long as a surety bond or trust fund remains in effect and shall ensure the financial responsibility of the freight forwarder. The requirements applicable to property broker surety bonds and

trust funds in § 387.307 shall apply to the surety bond or trust fund required by this paragraph (c).

#### § 387.413 [Suspended]

■ 72. Suspend § 387.413.

■ 73. Add § 387.413T to read as follows:

#### § 387.413T Forms and procedures.

(a) *Forms*. Endorsements for policies of insurance, surety bonds, certificates of insurance, applications to qualify as a self-insurer or for approval of other securities or agreements, and notices of cancellation must be in the form prescribed at subpart C of this part.

(b) *Procedure*. Certificates of insurance, surety bonds, and notices of cancellation must be filed with the FMCSA in triplicate.

(c) *Names*. Certificates of insurance and surety bonds shall be issued in the full name (including any trade name) of the individual, partnership (all partners named), corporation, or other person holding or to be issued the permit.

(d) *Cancellation*. Except as provided in paragraph (e) of this section, certificates of insurance, surety bonds, and other securities and agreements shall not be cancelled or withdrawn until 30 days after the FMCSA receives written notice from the insurance company, surety, freight forwarder, or other party, as the case may be.

(e) *Termination by replacement*. Certificates of insurance or surety bonds may be replaced by other certificates of insurance, surety bonds, or other security, and the liability of the retiring insurer or surety shall be considered as having terminated as of the replacement's effective date, if acceptable to the FMCSA.

(f) *Termination of Forms BMC-32 and BMC-34 for freight forwarders of property other than household goods*. Form BMC-32 endorsements and Form BMC-34 certificates of insurance issued to freight forwarders of property other than household goods that have been

accepted by the FMCSA under these rules will expire on March 21, 2011.

#### § 387.419 [Suspended]

■ 74. Suspend § 387.419.

■ 75. Add § 387.419T to read as follows:

#### § 387.419T Electronic filing of surety bonds, certificates of insurance and cancellations.

Insurers may, at their option and in accordance with the requirements and procedures set forth at § 387.323T, file certificates of insurance, surety bonds, and other securities and agreements electronically.

#### PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 76. The authority citation for part 390 is revised to read as follows:

**Authority:** 49 U.S.C. 508, 13301, 13902, 13908, 31132, 31133, 31136, 31151, 31502, 31504; sec. 114, Pub. L. 103-311, 108 Stat. 1673, 1677; sec. 217, Pub. L. 106-159, 113 Stat. 1748, 1767; sec. 4136, Pub. L. 109-59, 119 Stat. 1144, 1745; and 49 CFR 1.87.

#### § 390.3 [Suspended]

■ 77. Suspend § 390.3.

■ 78. Add § 390.3T to read as follows:

#### § 390.3T General applicability.

(a)(1) The rules in this subchapter are applicable to all employers, employees, and commercial motor vehicles that transport property or passengers in interstate commerce.

(2) The rules in 49 CFR 386.12(e) and 390.6 prohibiting the coercion of drivers of commercial motor vehicles operating in interstate commerce:

(i) To violate certain safety regulations are applicable to all motor carriers, shippers, receivers, and transportation intermediaries; and

(ii) To violate certain commercial regulations are applicable to all operators of commercial motor vehicles.

(b) The rules in part 383 of this chapter, Commercial Driver's License Standards; Requirements and Penalties, are applicable to every person who operates a commercial motor vehicle, as defined in § 383.5 of this subchapter, in interstate or intrastate commerce and to all employers of such persons.

(c) The rules in part 387 of this chapter, Minimum Levels of Financial Responsibility for Motor Carriers, are applicable to motor carriers as provided in § 387.3 or § 387.27 of this subchapter.

(d) *Additional requirements.* Nothing in this subchapter shall be construed to prohibit an employer from requiring and enforcing more stringent requirements relating to safety of operation and employee safety and health.

(e) *Knowledge of and compliance with the regulations.* (1) Every employer shall be knowledgeable of and comply with all regulations contained in this subchapter which are applicable to that motor carrier's operations.

(2) Every driver and employee shall be instructed regarding, and shall comply with, all applicable regulations contained in this subchapter.

(3) All motor vehicle equipment and accessories required by this subchapter shall be maintained in compliance with all applicable performance and design criteria set forth in this subchapter.

(f) *Exceptions.* Unless otherwise specifically provided, the rules in this subchapter do not apply to—

(1) All school bus operations as defined in § 390.5T, except for the provisions of §§ 391.15(e) and (f), 392.80, and 392.82 of this chapter.

(2) Transportation performed by the Federal government, a State, or any political subdivision of a State, or an agency established under a compact between States that has been approved by the Congress of the United States;

(3) The occasional transportation of personal property by individuals not for compensation nor in the furtherance of a commercial enterprise;

(4) The transportation of human corpses or sick and injured persons;

(5) The operation of fire trucks and rescue vehicles while involved in emergency and related operations;

(6) The operation of commercial motor vehicles designed or used to transport between 9 and 15 passengers (including the driver), not for direct compensation, provided the vehicle does not otherwise meet the definition of a commercial motor vehicle, except that motor carriers and drivers operating such vehicles are required to comply with §§ 390.15, 390.19T, 390.21T(a) and (b)(2), 391.15(e) and (f), 392.80 and 392.82 of this chapter.

(7) Either a driver of a commercial motor vehicle used primarily in the transportation of propane winter heating fuel or a driver of a motor vehicle used to respond to a pipeline emergency, if such regulations would prevent the driver from responding to an emergency condition requiring immediate response as defined in § 390.5T.

(g) *Motor carriers that transport hazardous materials in intrastate commerce.* The rules in the following provisions of this subchapter apply to motor carriers that transport hazardous materials in intrastate commerce and to the motor vehicles that transport hazardous materials in intrastate commerce:

(1) Part 385, subparts A and E, of this chapter for carriers subject to the requirements of § 385.403 of this chapter.

(2) Part 386 of this chapter, Rules of practice for motor carrier, broker, freight forwarder, and hazardous materials proceedings.

(3) Part 387 of this chapter, Minimum Levels of Financial Responsibility for Motor Carriers, to the extent provided in § 387.3 of this chapter.

(4) Section 390.19T, Motor carrier identification report, and § 390.21T, Marking of CMVs, for carriers subject to the requirements of § 385.403 of this chapter. Intrastate motor carriers operating prior to January 1, 2005, are excepted from § 390.19T(a)(1).

(h) *Intermodal equipment providers.* On and after December 17, 2009, the rules in the following provisions of this subchapter apply to intermodal equipment providers:

(1) Subpart F, Intermodal Equipment Providers, of part 385 of this chapter, Safety Fitness Procedures.

(2) Part 386 of this chapter, Rules of Practice for Motor Carrier, Intermodal Equipment Provider, Broker, Freight Forwarder, and Hazardous Materials Proceedings.

(3) This part, Federal Motor Carrier Safety Regulations; General, except § 390.15(b) concerning accident registers.

(4) Part 393 of this chapter, Parts and Accessories Necessary for Safe Operation.

(5) Part 396 of this chapter, Inspection, Repair, and Maintenance.

#### § 390.5 [Suspended]

■ 79. Suspend § 390.5.

■ 80. Add § 390.5T to read as follows:

#### § 390.5T Definitions.

Unless specifically defined elsewhere, in this subchapter:

*Accident* means—

(1) Except as provided in paragraph (2) of this definition, an occurrence

involving a commercial motor vehicle operating on a highway in interstate or intrastate commerce which results in:

(i) A fatality;

(ii) Bodily injury to a person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or

(iii) One or more motor vehicles incurring disabling damage as a result of the accident, requiring the motor vehicle(s) to be transported away from the scene by a tow truck or other motor vehicle.

(2) The term accident does not include:

(i) An occurrence involving only boarding and alighting from a stationary motor vehicle; or

(ii) An occurrence involving only the loading or unloading of cargo.

*Alcohol concentration (AC)* means the concentration of alcohol in a person's blood or breath. When expressed as a percentage it means grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

*Bus* means any motor vehicle designed, constructed, and/or used for the transportation of passengers, including taxicabs.

*Business district* means the territory contiguous to and including a highway when within any 600 feet along such highway there are buildings in use for business or industrial purposes, including but not limited to hotels, banks, or office buildings which occupy at least 300 feet of frontage on one side or 300 feet collectively on both sides of the highway.

*Charter transportation of passengers* means transportation, using a bus, of a group of persons who pursuant to a common purpose, under a single contract, at a fixed charge for the motor vehicle, have acquired the exclusive use of the motor vehicle to travel together under an itinerary either specified in advance or modified after having left the place of origin.

*Coerce or Coercion* means either—

(1) A threat by a motor carrier, shipper, receiver, or transportation intermediary, or their respective agents, officers or representatives, to withhold business, employment or work opportunities from, or to take or permit any adverse employment action against, a driver in order to induce the driver to operate a commercial motor vehicle under conditions which the driver stated would require him or her to violate one or more of the regulations, which the driver identified at least generally, that are codified at 49 CFR parts 171 through 173, 177 through 180, 380 through 383, or 390 through 399, or § 385.415 or § 385.421T of this chapter,



or the actual withholding of business, employment, or work opportunities or the actual taking or permitting of any adverse employment action to punish a driver for having refused to engage in such operation of a commercial motor vehicle; or

(2) A threat by a motor carrier, or its agents, officers or representatives, to withhold business, employment or work opportunities or to take or permit any adverse employment action against a driver in order to induce the driver to operate a commercial motor vehicle under conditions which the driver stated would require a violation of one or more of the regulations, which the driver identified at least generally, that are codified at 49 CFR parts 356, 360, or 365 through 379, or the actual withholding of business, employment or work opportunities or the actual taking or permitting of any adverse employment action to punish a driver for refusing to engage in such operation of a commercial motor vehicle.

*Commercial motor vehicle* means any self-propelled or towed motor vehicle used on a highway in interstate commerce to transport passengers or property when the vehicle—

(1) Has a gross vehicle weight rating or gross combination weight rating, or gross vehicle weight or gross combination weight, of 4,536 kg (10,001 pounds) or more, whichever is greater; or

(2) Is designed or used to transport more than 8 passengers (including the driver) for compensation; or

(3) Is designed or used to transport more than 15 passengers, including the driver, and is not used to transport passengers for compensation; or

(4) Is used in transporting material found by the Secretary of Transportation to be hazardous under 49 U.S.C. 5103 and transported in a quantity requiring placarding under regulations prescribed by the Secretary under 49 CFR, subtitle B, chapter I, subchapter C.

*Conviction* means an unvacated adjudication of guilt, or a determination that a person has violated or failed to comply with the law in a court of original jurisdiction or by an authorized administrative tribunal, an unvacated forfeiture of bail or collateral deposited to secure the person's appearance in court, a plea of guilty or nolo contendere accepted by the court, the payment of a fine or court cost, or violation of a condition of release without bail, regardless of whether or not the penalty is rebated, suspended, or prorated.

*Covered farm vehicle* means—

(1) A straight truck or articulated vehicle—

(i) Registered in a State with a license plate or other designation issued by the State of registration that allows law enforcement officials to identify it as a farm vehicle;

(ii) Operated by the owner or operator of a farm or ranch, or an employee or family member of a an owner or operator of a farm or ranch;

(iii) Used to transport agricultural commodities, livestock, machinery or supplies to or from a farm or ranch; and

(iv) Not used in for-hire motor carrier operations; however, for-hire motor carrier operations do not include the operation of a vehicle meeting the requirements of paragraphs (1)(i) through (iii) of this definition by a tenant pursuant to a crop share farm lease agreement to transport the landlord's portion of the crops under that agreement.

(2) Meeting the requirements of paragraphs (1)(i) through (iv) of this definition:

(i) With a gross vehicle weight or gross vehicle weight rating, whichever is greater, of 26,001 pounds or less may utilize the exemptions in § 390.39 anywhere in the United States; or

(ii) With a gross vehicle weight or gross vehicle weight rating, whichever is greater, of more than 26,001 pounds may utilize the exemptions in § 390.39 anywhere in the State of registration or across State lines within 150 air miles of the farm or ranch with respect to which the vehicle is being operated.

*Crash*. See accident.

*Direct assistance* means transportation and other relief services provided by a motor carrier or its driver(s) incident to the immediate restoration of essential services (such as, electricity, medical care, sewer, water, telecommunications, and telecommunication transmissions) or essential supplies (such as, food and fuel). It does not include transportation related to long-term rehabilitation of damaged physical infrastructure or routine commercial deliveries after the initial threat to life and property has passed.

*Direct compensation* means payment made to the motor carrier by the passengers or a person acting on behalf of the passengers for the transportation services provided, and not included in a total package charge or other assessment for highway transportation services.

*Disabling damage* means damage which precludes departure of a motor vehicle from the scene of the accident in its usual manner in daylight after simple repairs.

(1) *Inclusions*. Damage to motor vehicles that could have been driven,

but would have been further damaged if so driven.

(2) *Exclusions*. (i) Damage which can be remedied temporarily at the scene of the accident without special tools or parts.

(ii) Tire disablement without other damage even if no spare tire is available.

(iii) Headlamp or taillight damage.

(iv) Damage to turn signals, horn, or windshield wipers which makes them inoperative.

*Driveaway-towaway operation* means an operation in which an empty or unladen motor vehicle with one or more sets of wheels on the surface of the roadway is being transported:

(1) Between vehicle manufacturer's facilities;

(2) Between a vehicle manufacturer and a dealership or purchaser;

(3) Between a dealership, or other entity selling or leasing the vehicle, and a purchaser or lessee;

(4) To a motor carrier's terminal or repair facility for the repair of disabling damage (as defined in this section) following a crash; or

(5) To a motor carrier's terminal or repair facility for repairs associated with the failure of a vehicle component or system; or

(6) By means of a saddle-mount or tow-bar.

*Driver* means any person who operates any commercial motor vehicle.

*Driving a commercial motor vehicle while under the influence of alcohol* means committing any one or more of the following acts in a CMV: Driving a CMV while the person's alcohol concentration is 0.04 or more; driving under the influence of alcohol, as prescribed by State law; or refusal to undergo such testing as is required by any State or jurisdiction in the enforcement of Table 1 to § 383.51 or § 392.5(a)(2) of this subchapter.

*Electronic device* includes, but is not limited to, a cellular telephone; personal digital assistant; pager; computer; or any other device used to input, write, send, receive, or read text.

*Emergency* means any hurricane, tornado, storm (e.g. thunderstorm, snowstorm, icestorm, blizzard, sandstorm, etc.), high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, mud slide, drought, forest fire, explosion, blackout or other occurrence, natural or man-made, which interrupts the delivery of essential services (such as, electricity, medical care, sewer, water, telecommunications, and telecommunication transmissions) or essential supplies (such as, food and fuel) or otherwise immediately threatens human life or public welfare, provided

such hurricane, tornado, or other event results in:

(1) A declaration of an emergency by the President of the United States, the Governor of a State, or their authorized representatives having authority to declare emergencies; by the FMCSA Field Administrator for the geographical area in which the occurrence happens; or by other Federal, State or local government officials having authority to declare emergencies; or

(2) A request by a police officer for tow trucks to move wrecked or disabled motor vehicles.

*Emergency condition requiring immediate response* means any condition that, if left unattended, is reasonably likely to result in immediate serious bodily harm, death, or substantial damage to property. In the case of transportation of propane winter heating fuel, such conditions shall include (but are not limited to) the detection of gas odor, the activation of carbon monoxide alarms, the detection of carbon monoxide poisoning, and any real or suspected damage to a propane gas system following a severe storm or flooding. An “emergency condition requiring immediate response” does not include requests to refill empty gas tanks. In the case of a pipeline emergency, such conditions include (but are not limited to) indication of an abnormal pressure event, leak, release or rupture.

*Emergency relief* means an operation in which a motor carrier or driver of a commercial motor vehicle is providing direct assistance to supplement State and local efforts and capabilities to save lives or property or to protect public health and safety as a result of an emergency as defined in this section.

*Employee* means any individual, other than an employer, who is employed by an employer and who in the course of his or her employment directly affects commercial motor vehicle safety. Such term includes a driver of a commercial motor vehicle (including an independent contractor while in the course of operating a commercial motor vehicle), a mechanic, and a freight handler. Such term does not include an employee of the United States, any State, any political subdivision of a State, or any agency established under a compact between States and approved by the Congress of the United States who is acting within the course of such employment.

*Employer* means any person engaged in a business affecting interstate commerce who owns or leases a commercial motor vehicle in connection with that business, or assigns employees to operate it, but such terms does not

include the United States, any State, any political subdivision of a State, or an agency established under a compact between States approved by the Congress of the United States.

*Exempt intracity zone* means the geographic area of a municipality or the commercial zone of that municipality described in appendix F to this subchapter. The term “exempt intracity zone” does not include any municipality or commercial zone in the State of Hawaii. For purposes of § 391.62 of this chapter, a driver may be considered to operate a commercial motor vehicle wholly within an exempt intracity zone notwithstanding any common control, management, or arrangement for a continuous carriage or shipment to or from a point without such zone.

*Exempt motor carrier* means a person engaged in transportation exempt from economic regulation by the Federal Motor Carrier Safety Administration (FMCSA) under 49 U.S.C. 13506. “Exempt motor carriers” are subject to the safety regulations set forth in this subchapter.

*Farm vehicle driver* means a person who drives only a commercial motor vehicle that is—

- (1) Controlled and operated by a farmer as a private motor carrier of property;
- (2) Being used to transport either—
  - (i) Agricultural products; or
  - (ii) Farm machinery, farm supplies, or both, to or from a farm;
- (3) Not being used in the operation of a for-hire motor carrier;
- (4) Not carrying hazardous materials of a type or quantity that requires the commercial motor vehicle to be placarded in accordance with § 177.823 of this subtitle; and
- (5) Being used within 150 air-miles of the farmer’s farm.

*Farmer* means any person who operates a farm or is directly involved in the cultivation of land, crops, or livestock which—

- (1) Are owned by that person; or
- (2) Are under the direct control of that person.

*Fatality* means any injury which results in the death of a person at the time of the motor vehicle accident or within 30 days of the accident.

*Federal Motor Carrier Safety Administrator* means the chief executive of the Federal Motor Carrier Safety Administration, an agency within the Department of Transportation.

*For-hire motor carrier* means a person engaged in the transportation of goods or passengers for compensation.

*Gross combination weight rating (GCWR)* is the greater of:

(1) A value specified by the manufacturer of the power unit, if such value is displayed on the Federal Motor Vehicle Safety Standard (FMVSS) certification label required by the National Highway Traffic Safety Administration; or

(2) The sum of the gross vehicle weight ratings (GVWRs) or the gross vehicle weights (GVWs) of the power unit and the towed unit(s), or any combination thereof, that produces the highest value. Exception: The GCWR of the power unit will not be used to define a commercial motor vehicle when the power unit is not towing another vehicle.

*Gross vehicle weight rating (GVWR)* means the value specified by the manufacturer as the loaded weight of a single motor vehicle.

*Hazardous material* means a substance or material which has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated.

*Hazardous substance* means a material, and its mixtures or solutions, that is identified in the appendix to § 172.101 of this title, List of Hazardous Substances and Reportable Quantities, of this title when offered for transportation in one package, or in one transport motor vehicle if not packaged, and when the quantity of the material therein equals or exceeds the reportable quantity (RQ). This definition does not apply to petroleum products that are lubricants or fuels, or to mixtures or solutions of hazardous substances if in a concentration less than that shown in the table in § 171.8 of this title, based on the reportable quantity (RQ) specified for the materials listed in the appendix to § 172.101 of this title.

*Hazardous waste* means any material that is subject to the hazardous waste manifest requirements of the EPA specified in 40 CFR part 262 or would be subject to these requirements absent an interim authorization to a State under 40 CFR part 123, subpart F.

*Highway* means any road, street, or way, whether on public or private property, open to public travel. “Open to public travel” means that the road section is available, except during scheduled periods, extreme weather or emergency conditions, passable by four-wheel standard passenger cars, and open to the general public for use without restrictive gates, prohibitive signs, or regulation other than restrictions based on size, weight, or class of registration. Toll plazas of

public toll roads are not considered restrictive gates.

*Interchange* means—

(1) The act of providing intermodal equipment to a motor carrier pursuant to an intermodal equipment interchange agreement for the purpose of transporting the equipment for loading or unloading by any person or repositioning the equipment for the benefit of the equipment provider, but it does not include the leasing of equipment to a motor carrier for primary use in the motor carrier's freight hauling operations; or

(2) The act of providing a passenger-carrying commercial motor vehicle by one motor carrier of passengers to another such carrier, at a point which both carriers are authorized to serve, with which to continue a through movement.

(3) For property-carrying vehicles, see § 376.2 of this subchapter.

*Intermodal equipment* means trailing equipment that is used in the intermodal transportation of containers over public highways in interstate commerce, including trailers and chassis.

*Intermodal equipment interchange agreement* means the Uniform Intermodal Interchange and Facilities Access Agreement (UIIFA) or any other written document executed by an intermodal equipment provider or its agent and a motor carrier or its agent, the primary purpose of which is to establish the responsibilities and liabilities of both parties with respect to the interchange of the intermodal equipment.

*Intermodal equipment provider* means any person that interchanges intermodal equipment with a motor carrier pursuant to a written interchange agreement or has a contractual responsibility for the maintenance of the intermodal equipment.

*Interstate commerce* means trade, traffic, or transportation in the United States—

(1) Between a place in a State and a place outside of such State (including a place outside of the United States);

(2) Between two places in a State through another State or a place outside of the United States; or

(3) Between two places in a State as part of trade, traffic, or transportation originating or terminating outside the State or the United States.

*Intrastate commerce* means any trade, traffic, or transportation in any State which is not described in the term "interstate commerce."

*Lease*, as used in § 390.21T(f) and subpart F of this part, means a contract or arrangement in which a motor carrier

grants the use of a passenger-carrying commercial motor vehicle to another motor carrier, with or without a driver, for a specified period for the transportation of passengers, in exchange for compensation. The term lease includes an interchange, as defined in this section, or other agreement granting the use of a passenger-carrying commercial motor vehicle for a specified period, with or without a driver, whether or not compensation for such use is specified or required. For a definition of lease in the context of property-carrying vehicles, see § 376.2 of this subchapter.

*Lessee*, as used in subpart F of this part, means the motor carrier obtaining the use of a passenger-carrying commercial motor vehicle, with or without the driver, from another motor carrier. The term lessee includes a motor carrier obtaining the use of a passenger-carrying commercial motor vehicle from another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of lessee in the context of property-carrying vehicles, see § 376.2 of this subchapter.

*Lessor*, as used in subpart F of this part, means the motor carrier granting the use of a passenger-carrying commercial motor vehicle, with or without a driver, to another motor carrier. The term lessor includes a motor carrier granting the use of a passenger-carrying commercial motor vehicle to another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of lessor in the context of property-carrying vehicles, see § 376.2 of this subchapter.

*Medical examiner* means the following:

(1) For medical examinations conducted before May 21, 2014, a person who is licensed, certified, and/or registered, in accordance with applicable State laws and regulations, to perform physical examinations. The term includes but is not limited to, doctors of medicine, doctors of osteopathy, physician assistants, advanced practice nurses, and doctors of chiropractic.

(2) For medical examinations conducted on and after May 21, 2014, an individual certified by FMCSA and listed on the National Registry of Certified Medical Examiners in accordance with subpart D of this part.

*Medical variance* means a driver has received one of the following from

FMCSA that allows the driver to be issued a medical certificate:

(1) An exemption letter permitting operation of a commercial motor vehicle pursuant to part 381, subpart C, of this chapter or § 391.64 of this chapter;

(2) A skill performance evaluation certificate permitting operation of a commercial motor vehicle pursuant to § 391.49 of this chapter.

*Mobile telephone* means a mobile communication device that falls under or uses any commercial mobile radio service, as defined in regulations of the Federal Communications Commission, 47 CFR 20.3. It does not include two-way or Citizens Band Radio services.

*Motor carrier* means a for-hire motor carrier or a private motor carrier. The term includes a motor carrier's agents, officers and representatives as well as employees responsible for hiring, supervising, training, assigning, or dispatching of drivers and employees concerned with the installation, inspection, and maintenance of motor vehicle equipment and/or accessories. For purposes of this subchapter, this definition includes the terms employer, and exempt motor carrier.

*Motor vehicle* means any vehicle, machine, tractor, trailer, or semitrailer propelled or drawn by mechanical power and used upon the highways in the transportation of passengers or property, or any combination thereof determined by the Federal Motor Carrier Safety Administration, but does not include any vehicle, locomotive, or car operated exclusively on a rail or rails, or a trolley bus operated by electric power derived from a fixed overhead wire, furnishing local passenger transportation similar to street-railway service.

*Motor vehicle record* means the report of the driving status and history of a driver generated from the driver record, provided to users, such as, drivers or employers, and subject to the provisions of the Driver Privacy Protection Act, 18 U.S.C. 2721–2725.

*Multiple-employer driver* means a driver, who in any period of 7 consecutive days, is employed or used as a driver by more than one motor carrier.

*Operating authority* means the registration required by 49 U.S.C. 13902, 49 CFR part 365, 49 CFR part 368, and 49 CFR 392.9a.

*Operator*. See driver.

*Other terms*. Any other term used in this subchapter is used in its commonly accepted meaning, except where such other term has been defined elsewhere in this subchapter. In that event, the definition therein given shall apply.

*Out-of-service order* means a declaration by an authorized enforcement officer of a Federal, State, Canadian, Mexican, or local jurisdiction that a driver, a commercial motor vehicle, or a motor carrier operation is out of service pursuant to 49 CFR 386.72, 392.5, 392.9a, 395.13, or 396.9, or compatible laws, or the North American Standard Out-of-Service Criteria.

*Person* means any individual, partnership, association, corporation, business trust, or any other organized group of individuals.

*Previous employer* means any DOT regulated person who employed the driver in the preceding 3 years, including any possible current employer.

*Principal place of business* means the single location designated by the motor carrier, normally its headquarters, for purposes of identification under this subchapter. The motor carrier must make records required by parts 382, 387, 390, 391, 395, 396, and 397 of this subchapter available for inspection at this location within 48 hours (Saturdays, Sundays, and Federal holidays excluded) after a request has been made by a special agent or authorized representative of the Federal Motor Carrier Safety Administration.

*Private motor carrier* means a person who provides transportation of property or passengers, by commercial motor vehicle, and is not a for-hire motor carrier.

*Private motor carrier of passengers (business)* means a private motor carrier engaged in the interstate transportation of passengers which is provided in the furtherance of a commercial enterprise and is not available to the public at large.

*Private motor carrier of passengers (nonbusiness)* means private motor carrier involved in the interstate transportation of passengers that does not otherwise meet the definition of a private motor carrier of passengers (business).

*Radar detector* means any device or mechanism to detect the emission of radio microwaves, laser beams or any other future speed measurement technology employed by enforcement personnel to measure the speed of commercial motor vehicles upon public roads and highways for enforcement purposes. Excluded from this definition are radar detection devices that meet both of the following requirements:

(1) Transported outside the driver's compartment of the commercial motor vehicle. For this purpose, the driver's compartment of a passenger-carrying CMV shall include all space designed to

accommodate both the driver and the passengers; and

(2) Completely inaccessible to, inoperable by, and imperceptible to the driver while operating the commercial motor vehicle.

*Receiver or consignee* means a person who takes delivery from a motor carrier or driver of a commercial motor vehicle of property transported in interstate commerce or hazardous materials transported in interstate or intrastate commerce.

*Regional Director of Motor Carriers* means the Field Administrator, Federal Motor Carrier Safety Administration, for a given geographical area of the United States.

*Residential district* means the territory adjacent to and including a highway which is not a business district and for a distance of 300 feet or more along the highway is primarily improved with residences.

*School bus* means a passenger motor vehicle which is designed or used to carry more than 10 passengers in addition to the driver, and which the Secretary determines is likely to be significantly used for the purpose of transporting preprimary, primary, or secondary school students to such schools from home or from such schools to home.

*School bus operation* means the use of a school bus to transport only school children and/or school personnel from home to school and from school to home.

*Secretary* means the Secretary of Transportation.

*Shipper* means a person who tenders property to a motor carrier or driver of a commercial motor vehicle for transportation in interstate commerce, or who tenders hazardous materials to a motor carrier or driver of a commercial motor vehicle for transportation in interstate or intrastate commerce.

*Single-employer driver* means a driver who, in any period of 7 consecutive days, is employed or used as a driver solely by a single motor carrier. This term includes a driver who operates a commercial motor vehicle on an intermittent, casual, or occasional basis.

*Special agent*. See appendix B to this subchapter—Special agents.

*State* means a State of the United States and the District of Columbia and includes a political subdivision of a State.

*Texting* means manually entering alphanumeric text into, or reading text from, an electronic device.

(1) This action includes, but is not limited to, short message service, emailing, instant messaging, a command or request to access a World Wide Web

page, pressing more than a single button to initiate or terminate a voice communication using a mobile telephone, or engaging in any other form of electronic text retrieval or entry, for present or future communication.

(2) Texting does not include:

(i) Inputting, selecting, or reading information on a global positioning system or navigation system; or

(ii) Pressing a single button to initiate or terminate a voice communication using a mobile telephone; or

(iii) Using a device capable of performing multiple functions (e.g., fleet management systems, dispatching devices, smart phones, citizens band radios, music players, etc.) for a purpose that is not otherwise prohibited in this subchapter.

*Trailer* includes:

(1) Full trailer means any motor vehicle other than a pole trailer which is designed to be drawn by another motor vehicle and so constructed that no part of its weight, except for the towing device, rests upon the self-propelled towing motor vehicle. A semitrailer equipped with an auxiliary front axle (converter dolly) shall be considered a full trailer.

(2) Pole trailer means any motor vehicle which is designed to be drawn by another motor vehicle and attached to the towing motor vehicle by means of a "reach" or "pole," or by being "boomed" or otherwise secured to the towing motor vehicle, for transporting long or irregularly shaped loads such as poles, pipes, or structural members, which generally are capable of sustaining themselves as beams between the supporting connections.

(3) Semitrailer means any motor vehicle, other than a pole trailer, which is designed to be drawn by another motor vehicle and is constructed so that some part of its weight rests upon the self-propelled towing motor vehicle.

*Transportation intermediary* means a person who arranges the transportation of property or passengers by commercial motor vehicle in interstate commerce, or who arranges the transportation of hazardous materials by commercial motor vehicle in interstate or intrastate commerce, including but not limited to brokers and freight forwarders.

*Truck* means any self-propelled commercial motor vehicle except a truck tractor, designed and/or used for the transportation of property.

*Truck tractor* means a self-propelled commercial motor vehicle designed and/or used primarily for drawing other vehicles.

*Use a hand-held mobile telephone* means:

(1) Using at least one hand to hold a mobile telephone to conduct a voice communication;

(2) Dialing or answering a mobile telephone by pressing more than a single button; or

(3) Reaching for a mobile telephone in a manner that requires a driver to maneuver so that he or she is no longer in a seated driving position, restrained by a seat belt that is installed in accordance with 49 CFR 393.93 and adjusted in accordance with the vehicle manufacturer's instructions.

*United States* means the 50 States and the District of Columbia.

**§ 390.19 [SUSPENDED]**

■ 81. Suspend § 390.19.

■ 82. Add § 390.19T to read as follows:

**§ 390.19T Motor carrier identification reports for certain Mexico-domiciled motor carriers.**

(a) *Applicability.* Each motor carrier and intermodal equipment provider must file Form MCS-150, Form MCS-150B or Form MCS-150C with FMCSA as follows:

(1) A U.S.-, Canada-, Mexico-, or non-North America-domiciled motor carrier conducting operations in interstate commerce must file a Motor Carrier Identification Report, Form MCS-150.

(2) A motor carrier conducting operations in intrastate commerce and requiring a Safety Permit under 49 CFR part 385, subpart E, must file the Combined Motor Carrier Identification Report and HM Permit Application, Form MCS-150B.

(3) Each intermodal equipment provider that offers intermodal equipment for transportation in interstate commerce must file an Intermodal Equipment Provider Identification Report, Form MCS-150C.

(b) *Filing schedule.* Each motor carrier or intermodal equipment provider must file the appropriate form under paragraph (a) of this section at the following times:

(1) Before it begins operations; and

(2) Every 24 months, according to the following schedule:

USDOT No. ending in	Must file by last day of
1 .....	January.
2 .....	February.
3 .....	March.
4 .....	April.
5 .....	May.
6 .....	June.
7 .....	July.
8 .....	August.
9 .....	September.
0 .....	October.

(3) If the next-to-last digit of its USDOT Number is odd, the motor carrier or intermodal equipment provider shall file its update in every odd-numbered calendar year. If the next-to-last digit of the USDOT Number is even, the motor carrier or intermodal equipment provider shall file its update in every even-numbered calendar year.

(4) A person that fails to complete biennial updates to the information pursuant to paragraph (b)(2) of this section is subject to the penalties prescribed in 49 U.S.C. 521(b)(2)(B) or 49 U.S.C. 14901(a), as appropriate, and deactivation of its USDOT Number.

(c) *Availability of forms.* The forms described under paragraph (a) of this section and complete instructions are available from the FMCSA Web site at <http://www.fmcsa.dot.gov> (Keyword "MCS-150," or "MCS-150B," or "MCS-150C"); from all FMCSA Service Centers and Division offices nationwide; or by calling 1-800-832-5660.

(d) *Where to file.* The required form under paragraph (a) of this section must be filed with the FMCSA Office of Registration and Safety Information. The form may be filed electronically according to the instructions at the Agency's Web site, or it may be sent to Federal Motor Carrier Safety Administration, Office of Registration and Safety Information (MC-RS), 1200 New Jersey Avenue SE., Washington, DC 20590.

(e) *Special instructions for for-hire motor carriers.* A for-hire motor carrier should submit the Form MCS-150, or Form MCS-150B, along with its application for operating authority (Form OP-1, OP-1(MX), OP-1(NNA) or OP-2), to the appropriate address referenced on that form, or may submit it electronically or by mail separately to the address mentioned in paragraph (d) of this section.

(f) Only the legal name or a single trade name of the motor carrier or intermodal equipment provider may be used on the forms under paragraph (a) of this section (Form MCS-150, MCS-150B, or MCS-150C).

(g) A motor carrier or intermodal equipment provider that fails to file the form required under paragraph (a) of this section, or furnishes misleading information or makes false statements upon the form, is subject to the penalties prescribed in 49 U.S.C. 521(b)(2)(B).

(h)(1) Upon receipt and processing of the form described in paragraph (a) of this section, FMCSA will issue the motor carrier or intermodal equipment provider an identification number (USDOT Number).

(2) The following applicants must additionally pass a pre-authorization safety audit as described below before being issued a USDOT Number:

(i) A Mexico-domiciled motor carrier seeking to provide transportation of property or passengers in interstate commerce between Mexico and points in the United States beyond the municipalities and commercial zones along the United States-Mexico international border must pass the pre-authorization safety audit under § 365.507T of this subchapter. The Agency will not issue a USDOT Number until expiration of the protest period provided in § 365.115 of this subchapter or—if a protest is received—after FMCSA denies or rejects the protest.

(ii) A non-North America-domiciled motor carrier seeking to provide transportation of property or passengers in interstate commerce within the United States must pass the pre-authorization safety audit under § 385.607T(c) of this subchapter. The Agency will not issue a USDOT Number until expiration of the protest period provided in § 365.115 of this subchapter or—if a protest is received—after FMCSA denies or rejects the protest.

(3) The motor carrier must display the number on each self-propelled CMV, as defined in § 390.5T, along with the additional information required by § 390.21T.

(4) The intermodal equipment provider must identify each unit of interchanged intermodal equipment by its assigned USDOT number.

(i) A motor carrier that registers its vehicles in a State that participates in the Performance and Registration Information Systems Management (PRISM) program (authorized under section 4004 of the Transportation Equity Act for the 21st Century [Public Law 105-178, 112 Stat. 107]) is exempt from the requirements of this section, provided it files all the required information with the appropriate State office.

**§ 390.21 [Suspended]**

■ 83. Suspend § 390.21.

■ 84. Add § 390.21T to read as follows:

**§ 390.21T Marking of self-propelled CMVs and intermodal equipment.**

(a) *General.* Every self-propelled CMV subject to this subchapter must be marked as specified in paragraphs (b), (c), and (d) of this section, and each unit of intermodal equipment interchanged or offered for interchange to a motor carrier by an intermodal equipment provider subject to this subchapter must be marked as specified in paragraph (g) of this section.

(b) *Nature of marking.* The marking must display the following information:

(1) The legal name or a single trade name of the motor carrier operating the self-propelled CMV, as listed on the motor carrier identification report (Form MCS-150) and submitted in accordance with § 390.19T.

(2) The identification number issued by FMCSA to the motor carrier or intermodal equipment provider, preceded by the letters “USDOT.”

(3) If the name of any person other than the operating carrier appears on the CMV, the name of the operating carrier must be followed by the information required by paragraphs (b)(1) and (2) of this section, and be preceded by the words “operated by.”

(4) Other identifying information may be displayed on the vehicle if it is not inconsistent with the information required by this paragraph (b).

(c) *Size, shape, location, and color of marking.* The marking must—

(1) Appear on both sides of the self-propelled CMV;

(2) Be in letters that contrast sharply in color with the background on which the letters are placed;

(3) Be readily legible, during daylight hours, from a distance of 50 feet (15.24 meters) while the CMV is stationary; and

(4) Be kept and maintained in a manner that retains the legibility required by paragraph (c)(3) of this section.

(d) *Construction and durability.* The marking may be painted on the CMV or may consist of a removable device, if that device meets the identification and legibility requirements of paragraph (c) of this section, and such marking must be maintained as required by paragraph (c)(4) of this section.

(e) *Rented property-carrying commercial motor vehicles.* A motor carrier operating a self-propelled property-carrying commercial motor vehicle under a rental agreement having a term not in excess of 30 calendar days meets the requirements of this section if:

(1) The CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section; or

(2) The CMV is marked as set forth in paragraphs (e)(2)(i) through (iv) of this section:

(i) The legal name or a single trade name of the lessor is displayed in accordance with paragraphs (c) and (d) of this section.

(ii) The lessor’s identification number preceded by the letters “USDOT” is displayed in accordance with paragraphs (c) and (d) of this section.

(iii) The rental agreement entered into by the lessor and the renting motor

carrier conspicuously contains the following information:

(A) The name and complete physical address of the principal place of business of the renting motor carrier;

(B) The identification number issued the renting motor carrier by the FMCSA, preceded by the letters “USDOT,” if the motor carrier has been issued such a number. In lieu of the identification number required in this paragraph (e)(2)(iii)(B), the following may be shown in the rental agreement:

(1) Information which indicates whether the motor carrier is engaged in “interstate” or “intrastate” commerce; and

(2) Information which indicates whether the renting motor carrier is transporting hazardous materials in the rented CMV; and

(C) The sentence: “This lessor cooperates with all Federal, State, and local law enforcement officials nationwide to provide the identity of customers who operate this rental CMV”.

(iv) The rental agreement entered into by the lessor and the renting motor carrier is carried on the rental CMV during the full term of the rental agreement. See the leasing regulations at 49 CFR part 376 for information that should be included in all leasing documents.

(f) *Leased and interchanged passenger-carrying commercial motor vehicles.* A motor carrier operating a leased or interchanged passenger-carrying commercial motor vehicle meets the requirements of this section if:

(1) The passenger-carrying CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section, except that marking is required only on the right (curb) side of the vehicle; and

(2) The passenger-carrying CMV is marked with a single placard, sign, or other device affixed to the right (curb) side of the vehicle on or near the front passenger door. The placard, sign or device must display the legal name or a single trade name of the motor carrier operating the CMV and the motor carrier’s USDOT number, preceded by the words “Operated by.”

(g) *Driveaway services.* In driveaway services, a removable device may be affixed on both sides or at the rear of a single driven vehicle. In a combination driveaway operation, the device may be affixed on both sides of any one unit or at the rear of the last unit. The removable device must display the legal name or a single trade name of the motor carrier and the motor carrier’s USDOT number.

(h) *Intermodal equipment.* (1) The requirements for marking intermodal equipment apply to each intermodal equipment provider, as defined in § 390.5T, that interchanges or offers for interchange intermodal equipment to a motor carrier.

(2) Each unit of intermodal equipment interchanged or offered for interchange to a motor carrier by an intermodal equipment provider subject to this subchapter must identify the intermodal equipment provider.

(3) The intermodal equipment provider must be identified by its legal name or a single trade name and the identification number issued by FMCSA, preceded by the letters “USDOT.”

(4) The intermodal equipment must be identified as follows, using any one of the following methods:

(i) The identification marking must appear on the curb side of the item of equipment. It must be in letters that contrast sharply in color with the background on which the letters are placed. The letters must be readily legible, during daylight hours, from a distance of 50 feet (15.24 meters) while the CMV is stationary; and be kept and maintained in a manner that retains this legibility; or

(ii) The identification marking must appear on a label placed upon the curb side of the item of equipment. The label must be readily visible and legible to an inspection official during daylight hours when the vehicle is stationary. The label must be a color that contrasts sharply with the background on which it is placed, and the letters must also contrast sharply in color with the background of the label. The label must be kept and maintained in a manner that retains this legibility; or

(iii) The USDOT number of the intermodal equipment provider must appear on the interchange agreement so that it is clearly identifiable to an inspection official. The interchange agreement must include additional information to identify the specific item of intermodal equipment (such as the Vehicle Identification Number (VIN) and 4-character Standard Carrier Alpha Code (SCAC) code and 6-digit unique identifying number); or

(iv) The identification marking must be shown on a document placed in a weathertight compartment affixed to the frame of the item of intermodal equipment. The color of the letters used in the document must contrast sharply in color with the background of the document. The document must include additional information to identify the specific item of intermodal equipment (such as the VIN and 4-character SCAC

code and 6-digit unique identifying number).

(v) The USDOT number of the intermodal equipment provider is maintained in a database that is available via real-time internet and telephonic access. The database must:

(A) Identify the name and USDOT number of the intermodal equipment provider responsible for the intermodal equipment, in response to an inquiry that includes:

(i) SCAC plus trailing digits; or  
(ii) License plate number and State of license; or  
(iii) VIN of the item of intermodal equipment.

(B) Offer read-only access for inquiries on individual items of intermodal equipment, without requiring advance user registration, a password, or a usage fee.

#### § 390.40 [SUSPENDED]

■ 85. Suspend § 390.40.

■ 86. Add § 390.40T to read as follows:

#### § 390.40T What responsibilities do intermodal equipment providers have under the Federal Motor Carrier Safety Regulations (49 CFR parts 350 through 399)?

An intermodal equipment provider must—

(a) Identify its operations to the FMCSA by filing the Form MCS-150C required by § 390.19T.

(b) Mark its intermodal equipment with the USDOT number as required by § 390.21T before tendering the equipment to a motor carrier.

(c) Systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, in a manner consistent with § 396.3(a)(1) of this chapter, as applicable, all

intermodal equipment intended for interchange with a motor carrier.

(d) Provide intermodal equipment intended for interchange that is in safe and proper operating condition.

(e) Maintain a system of driver vehicle inspection reports submitted to the intermodal equipment provider as required by § 396.11 of this chapter.

(f) Maintain a system of inspection, repair, and maintenance records as required by § 396.3(b)(3) of this chapter for equipment intended for interchange with a motor carrier.

(g) Periodically inspect equipment intended for interchange, as required under § 396.17 of this chapter.

(h) At facilities at which the intermodal equipment provider makes intermodal equipment available for interchange, have procedures in place, and provide sufficient space, for drivers to perform a pre-trip inspection of tendered intermodal equipment.

(i) At facilities at which the intermodal equipment provider makes intermodal equipment available for interchange, develop and implement procedures to repair any equipment damage, defects, or deficiencies identified as part of a pre-trip inspection, or replace the equipment, prior to the driver's departure. The repairs or replacement must be made after being notified by a driver of such damage, defects, or deficiencies.

(j) Refrain from placing intermodal equipment in service on the public highways if that equipment has been found to pose an imminent hazard, as defined in § 386.72(b)(3) of this chapter.

#### Subpart E—[SUSPENDED]

■ 87. Suspend subpart E, consisting of §§ 390.201 through 390.209.

■ 88. Add a new subpart E, consisting of § 390.200T, to read as follows:

#### Subpart E—URS Online Application

##### § 390.200T USDOT Registration.

(a) *Purpose.* This section establishes who must register with FMCSA using the Form MCSA-1, the URS online application, beginning January 14, 2017.

(b) *Applicability.* Notwithstanding any other provisions of this part or 49 CFR 385.305T(b)(2), a new applicant private motor carrier or new applicant exempt for-hire motor carrier subject to the requirements of this subchapter must file Form MCSA-1 with FMCSA to identify its operations with the Federal Motor Carrier Safety Administration for safety oversight. Form MCSA-1 is the URS online application, and both the application and its instructions are available from the FMCSA Web site at <http://www.fmcsa.dot.gov/urs>.

(c) *Definition.* For purposes of this section, a “new applicant” is an entity applying for operating authority registration and a USDOT number who does not at the time of application have an active registration or USDOT, Motor Carrier (MC), Mexican owned or controlled (MX), or Freight Forwarder (FF) number, and who has never had an active registration or USDOT, MC, MX, or FF number.

Issued under authority delegated under 49 CFR 1.87 on: December 23, 2016.

**T.F. Scott Darling III,**

*Administrator.*

[FR Doc. 2016-31706 Filed 1-13-17; 8:45 am]

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Part VII

## The President

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Executive Order 13758—Amending Executive Order 11016 To Update Eligibility Criteria for Award of the Purple Heart

Executive Order 13759—Designating the World Organisation for Animal Health as a Public International Organization Entitled To Enjoy Certain Privileges, Exemptions, and Immunities

Executive Order 13760—Exclusions From the Federal Labor-Management Relations Program



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# Presidential Documents

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**Title 3—****Executive Order 13758 of January 12, 2017****The President****Amending Executive Order 11016 To Update Eligibility Criteria for Award of the Purple Heart**

By the authority vested in me as President and as Commander in Chief of the armed forces by the Constitution and the laws of the United States of America, Executive Order 11016 of April 25, 1962, as amended, is further amended as follows:

**Section 1.** Paragraph 1 is amended to read as follows:

“1. The Secretary of a military department, or the Secretary of Homeland Security with regard to the Coast Guard when not operating as a service in the Navy, shall, in the name of the President of the United States, award the Purple Heart, with suitable ribbons and appurtenances, to any member or former member of the armed forces under the jurisdiction of that department who, while serving as a member of the armed forces, has been, or may hereafter be, wounded:

- (a) in any action against an enemy of the United States;
- (b) in any action with an opposing armed force of a foreign country in which the armed forces of the United States are or have been engaged;
- (c) while serving with friendly foreign forces engaged in an armed conflict against an opposing armed force in which the United States is not a belligerent party;
- (d) as the result of an act of any such enemy or opposing armed force;
- (e) as the result of an act of any hostile foreign force;
- (f) while being taken captive or while being held as a prisoner of war, and for purposes of this paragraph a person is considered a prisoner of war if the person is eligible for the Prisoner of War Medal pursuant to section 1128 of title 10, United States Code;
- (g) after March 28, 1973, as a result of an international terrorist attack against the United States or a foreign nation friendly to the United States, recognized as such an attack for the purposes of this order by the Secretary of the department concerned, or jointly by the Secretaries of the departments concerned if persons from more than one department are wounded in the attack;
- (h) after March 28, 1973, as a result of military operations, while serving outside the territory of the United States as part of a peacekeeping force;
- (i) after September 10, 2001, in an attack that was motivated or inspired by a foreign terrorist organization, which the Secretary of the department concerned shall treat in the same manner as an international terrorist attack, provided the attack specifically targeted the member due to his or her military service as provided in section 1129a of title 10, United States Code; or
- (j) after December 6, 1941, by friendly weapon fire while directly engaged in armed conflict, other than as the result of an act of an enemy of the United States, an opposing armed force, or hostile foreign force.”.

**Sec. 2.** Paragraph 2 is amended to read as follows:

“2. The Secretary of a military department, or the Secretary of Homeland Security with regard to the Coast Guard when not operating as a service in the Navy, shall, in the name of the President of the United States,

award the Purple Heart, with suitable ribbons and appurtenances, posthumously, to any member of the armed forces under the jurisdiction of that department covered by, and under the circumstances described in:

(a) paragraphs 1(a)–(f) who, after April 5, 1917;

(b) paragraphs 1(g)–(h) who, after March 28, 1973;

(c) paragraph 1(i) who, after September 10, 2001; or

(d) paragraph 1(j) who, after December 6, 1941, has been, or may hereafter be, killed, or who has died or may hereafter die after being wounded.”.

**Sec. 3.** Paragraph 3 is amended by inserting “been of such severity that it” after “must have”.

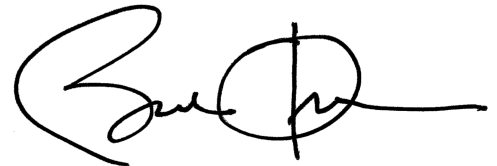
**Sec. 4.** Paragraphs 4, 5, 6, 7, and 8 are redesignated as paragraphs 5, 6, 7, 8, and 9, respectively.

**Sec. 5.** The following new paragraph 4 is inserted after paragraph 3:

“4. The Purple Heart is not authorized for a wound or death that results from the willful misconduct of the member.”.

**Sec. 6.** Paragraph 6, as redesignated, is amended by striking “paragraph 4” and inserting in lieu thereof “paragraph 5”.

**Sec. 7.** This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", written in a cursive style.

THE WHITE HOUSE,  
January 12, 2017.

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## Presidential Documents

Executive Order 13759 of January 12, 2017

### **Designating the World Organisation for Animal Health as a Public International Organization Entitled To Enjoy Certain Privileges, Exemptions, and Immunities**

**Section 1. *Designation.*** By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 1 of the International Organizations Immunities Act (22 U.S.C. 288), and having found that the World Organisation for Animal Health (also known by its historical acronym OIE) is a public international organization in which the United States participates within the meaning of the International Organizations Immunities Act, I hereby designate the World Organisation for Animal Health as a public international organization entitled to enjoy the privileges, exemptions, and immunities provided by the International Organizations Immunities Act. This designation is not intended to abridge in any respect privileges, exemptions, or immunities that such organization otherwise may have acquired or may acquire by law.

**Sec. 2. *General Provisions.*** (a) Nothing in this order shall be construed to impair or otherwise affect:

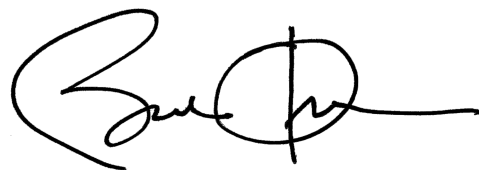
(1) the authority granted by law to an executive department, agency, or the head thereof; or

(2) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) This order is not intended to, and does not, impair any right or benefit, substantive or procedural, enforceable at law or in equity that arises as a consequence of the designation in section 1 of this order.

A handwritten signature in black ink, appearing to be "Donald Trump", written in a cursive style.

THE WHITE HOUSE,  
*January 12, 2017.*

[FR Doc. 2017-01168  
Filed 1-13-17; 11:15 am]  
Billing code 3295-F7-P

## Presidential Documents

Executive Order 13760 of January 12, 2017

### Exclusions From the Federal Labor-Management Relations Program

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 7103(b)(1) of title 5, United States Code, and in order to reflect the effects of the reorganization and restructuring of the Department of Defense on its agencies and subdivisions exempted from coverage under the Federal Labor-Management Relations Program, it is hereby ordered as follows:

**Section 1. Determinations.** The agencies and subdivisions of the Department of Defense set forth in section 2 of this order are hereby determined to have as a primary function intelligence, counterintelligence, investigative, or national security work. It is further determined that chapter 71 of title 5, United States Code, cannot be applied to these subdivisions in a manner consistent with national security requirements and considerations.

**Sec. 2. Department of Defense.** Executive Order 12171 of November 19, 1979, as amended, is further amended by:

(a) revising section 1–204 to read as follows:

“1–204. Agencies or subdivisions of the Department of the Army, Department of Defense:

(a) Office of the Deputy Chief of Staff, G–2 (Intelligence), and all G–2 Intelligence offices within Army Commands, Army Service Component Commands, and Direct Reporting Units.

(b) United States Army Intelligence and Security Command.

(c) The following subdivisions of the United States Army Cyber Command (ARCYBER) and Second Army:

(1) Headquarters, United States ARCYBER and Second Army.

(2) Joint Forces Headquarters—Cyber.

(3) Army Cyber Operations and Integration Center.

(d) United States Army Intelligence Center of Excellence (USAICoE), United States Army Training and Doctrine Command (TRADOC).

(e) United States Army Cyber Protection Brigade, United States Army Network Enterprise Technology Command.

(f) 114th Signal Battalion, 21st Signal Brigade, United States Army Network Enterprise Technology Command.

(g) 302nd Signal Battalion, 21st Signal Brigade, United States Army Network Enterprise Technology Command.

(h) United States Army Criminal Investigation Command (USACIDC).

(i) United States Army Special Operations Command (USASOC).

(j) Rapid Equipping Force (REF), United States Army Training and Doctrine Command (TRADOC).

(k) Asymmetric Warfare Group (AWG), United States Army Training and Doctrine Command (TRADOC).”;

(b) revising section 1–205 to read as follows:

“1–205. Agencies or subdivisions of the Department of the Navy, Department of Defense:



(a) Office of the Director of Naval Intelligence, and all Intelligence offices within Navy Commands, Navy Service Component Commands, and Direct Reporting Units, including the following:

- (1) Naval Intelligence Activity.
- (2) Office of Naval Intelligence.
- (3) Farragut Technical Analysis Center.
- (4) Nimitz Operational Intelligence Center.
- (5) Hopper Information Services Center.
- (6) Kennedy Irregular Warfare Center.
- (7) Brooks Center for Maritime Engagement.

(b) Naval Criminal Investigative Service.

(c) United States Fleet Cyber Command.

(d) Headquarters, Marine Corps Intelligence Department and subordinate activities, United States Marine Corps.

(e) Marine Forces Cyber Command, United States Marine Corps.

(f) Naval Computer and Telecommunications Station, San Diego, Detachment, Naval Strategic Communications Unit, Tinker Air Force Base.

(g) Naval Information Force Reserve, Navy Reserve Force.

(h) Center for Information Warfare Training, Naval Education and Training Command.

(i) Naval Special Warfare Command (NSW).

(j) Marine Special Operations Command (MARSOC).

(k) Navy Information Operations Commands and Detachments.

(l) Naval Communications Security Material System.”;

(c) revising section 1–206 to read as follows:

“1–206. Agencies or subdivisions of the Department of the Air Force, Department of Defense:

(a) Headquarters, 24th Air Force and Air Forces Cyber, Joint Force Headquarters, Air Force Space Command, and the following elements under its operational control:

- (1) 67th Cyberspace Wing.
- (2) 624th Operations Center.
- (3) The following subdivisions of the 688th Cyberspace Operations Wing:
  - (A) 318th Cyberspace Operations Group.
  - (B) 688th Cyberspace Operations Group.
- (4) 5th Combat Communications Group.

(b) Headquarters, 25th Air Force, Air Combat Command, and the following wings, groups, and elements under the operational control of the 25th Air Force:

- (1) 70th Intelligence, Surveillance and Reconnaissance Wing.
- (2) 363rd Intelligence, Surveillance and Reconnaissance Wing.
- (3) 480th Intelligence, Surveillance and Reconnaissance Wing.
- (4) 625th Operations Center.
- (5) The following subdivisions of the 9th Reconnaissance Wing:
  - (A) 9th Operations Group.
  - (B) 69th Reconnaissance Group.
- (6) 55th Operations Group, 55th Wing.

(c) Air Force Technical Applications Center (AFTAC), 25th Air Force, Air Combat Command.

(d) Office of the Deputy Chief of Staff, Intelligence, Surveillance and Reconnaissance (A2), Headquarters, United States Air Force, and all A2 staff within Air Force Commands, Air Force Service Component Commands, Field Operating Agencies, and Direct Reporting Units.

(e) National Air and Space Intelligence Center and all elements under its operational control.

(f) Air Force Special Operations Command (AFSOC), with the exception of the following subdivisions:

(1) The following groups of the 1st Special Operations Wing, Hurlburt Field, Florida:

- (A) Mission Support Group.
- (B) Medical Group.

(2) The following groups of the 27th Special Operations Wing, Cannon Air Force Base, New Mexico:

- (A) Mission Support Group.
- (B) Medical Group.

(g) Air Force Office of Special Investigations.

(h) 17th Training Wing, Air Education and Training Command, Goodfellow Air Force Base, Texas.”;

(d) revising section 1–207 to read as follows:

“1–207. Defense Intelligence Agency, Department of Defense.”;

(e) revising section 1–208 to read as follows:

“1–208. Defense Security Service, Department of Defense.”;

(f) revising section 1–212 to read as follows:

“1–212. Agencies or subdivisions under the authority of the Chairman of the Joint Chiefs of Staff and the Commanders of the Combatant Commands, Department of Defense.

(a) Office of the Chairman of the Joint Chiefs of Staff (OCJCS) and the Joint Staff.

(b) United States Africa Command (USAFRICOM).

(c) United States Central Command (USCENTCOM).

(d) United States European Command (USEUCOM).

(e) United States Pacific Command (USPACOM).

(f) United States Southern Command (USSOUTHCOM).

(g) North American Aerospace Defense Command (NORAD).

(h) United States Northern Command (USNORTHCOM).

(i) Headquarters, United States Transportation Command (USTRANSCOM), and its subordinate command, the Joint Enabling Capabilities Command.

(j) United States Strategic Command (USSTRATCOM) and all components, centers, or sub-unified commands currently assigned to USSTRATCOM, including the following:

(1) United States Cyber Command (USCYBERCOM).

(2) Joint Functional Component Command—Global Strike (JFCC GS).

(3) Joint Functional Component Command—Space (JFCC Space).

(4) Joint Functional Component Command—Integrated Missile Defense (JFCC IMD).

(5) Joint Functional Component Command—Intelligence, Surveillance and Reconnaissance (JFCC ISR).

(6) USSTRATCOM Center for Combating Weapons of Mass Destruction (SCC WMD).

(7) Standing Joint Force Headquarters for Elimination (SJFHQ-E).

(8) Joint Warfare Analysis Center (JWAC).

(k) United States Special Operations Command (USSOCOM) and all components and sub-unified commands under its administrative and operational control, including the following:

(1) Components:

(A) Marine Special Operations Command (MARSOC).

(B) Naval Special Warfare Command (NSW).

(C) Air Force Special Operations Command (AFSOC), with the exception of the following subdivisions:

(i) The following groups of the 1st Special Operations Wing, Hurlburt Field, Florida:

(I) Mission Support Group.

(II) Medical Group.

(ii) The following groups of the 27th Special Operations Wing, Cannon Air Force Base, New Mexico:

(I) Mission Support Group.

(II) Medical Group.

(D) United States Army Special Operations Command (USASOC).

(2) Sub-unified Commands:

(A) Joint Special Operations Command (JSOC).

(B) Special Operations Command Korea (SOCKOR).

(C) Special Operations Command Europe (SOCEUR).

(D) Special Operations Command South (SOCSOUTH).

(E) Special Operations Command Pacific (SOCPAC).

(F) Special Operations Command Africa (SOCAFRICA).

(G) Special Operations Command Central (SOCCENT).

(H) Special Operations Command North (SOCNORTH).”;

(g) revising section 1–215 to read as follows:

“Sec. 1–215. National Geospatial-Intelligence Agency (NGA), Department of Defense.”; and

(h) inserting after section 1–216 the following new sections:

“1–217. Defense Advanced Research Projects Agency, Department of Defense.

1–218. National Reconnaissance Office, Department of Defense.

1–219. Office of the Under Secretary of Defense for Intelligence, Department of Defense.

1–220. Field Detachment, Defense Contract Audit Agency, Department of Defense.

1–221. Special Programs Directorate, Defense Contract Management Agency, Department of Defense.

1–222. The following subdivisions of the Defense Information Systems Agency, Department of Defense:

(a) Joint Force Headquarters—Department of Defense Information Networks.

(b) White House Communications Agency.

1–223. The following subdivisions of the Defense Logistics Agency, Department of Defense:

(a) Defense Logistics Agency Intelligence.

(b) Joint Logistics Operations Center.

(c) Computer Emergency Response Team and Incident Response Branch.

1–224. Strategic Capabilities Office, Department of Defense.”.

**Sec. 3. General Provisions.** (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof, or the status of that department or agency within the Federal Government; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", written in a cursive style.

THE WHITE HOUSE,  
*January 12, 2017.*

# Reader Aids

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Vol. 82, No. 10

Tuesday, January 17, 2017

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## FEDERAL REGISTER PAGES AND DATE, JANUARY

1-710.....	3
711-1138.....	4
1139-1592.....	5
1593-2192.....	6
2193-2848.....	9
2849-3130.....	10
3131-3600.....	11
3601-4148.....	12
4149-4768.....	13
4769-5330.....	17

## CFR PARTS AFFECTED DURING JANUARY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

### 3 CFR

**Proclamations:**

9558.....	1139
9559.....	1149
9560.....	1157
9561.....	1159
9562.....	1161

**Executive Orders:**

11016 (amended by 13758).....	5321
12171 (amended by 13760).....	5325
13694 (amended by 13757).....	1
13757.....	1
13758.....	5321
13759.....	5323
13760.....	5325

### 5 CFR

2411.....	2849
9301.....	711

**Proposed Rules:**

532.....	3677
9401.....	2921

### 7 CFR

210.....	2193
220.....	2193
271.....	2010
272.....	2010
273.....	2010
274.....	2010
275.....	2010
276.....	2010
277.....	2010
278.....	2010
279.....	2010
280.....	2010
281.....	2010
282.....	2010
283.....	2010
285.....	2010

### Proposed Rules:

65.....	4198
250.....	1231
319.....	4798
1260.....	4203
3201.....	4206

### 8 CFR

103.....	5238
212.....	5238
235.....	4769
274a.....	5238
1235.....	4771

### Proposed Rules:

204.....	3211, 4738
216.....	3211, 4738

### 9 CFR

201.....	2193
----------	------

### 10 CFR

429.....	1052, 1426
430.....	1426, 1786
431.....	1052
435.....	2857

### Proposed Rules:

430.....	1608
----------	------

### 12 CFR

1083.....	3601
-----------	------

### Proposed Rules:

1805.....	2251
-----------	------

### 13 CFR

312.....	3131
----------	------

### 14 CFR

Ch. I.....	3606
1.....	2193
23.....	1163, 2193
25.....	2193
27.....	2193
29.....	2193
39...5, 7, 10, 12, 712, 716, 718, 1170, 1172, 1175, 1179, 1593, 1595, 3137, 3140, 3143, 3146, 4773, 4775, 4778	

61.....	2193, 3149
68.....	3149
71.....	720, 1181, 2868, 2870, 2871, 2873, 3167, 4149

91.....	2193, 3149
97.....	3603, 3605
121.....	2193
125.....	2193
135.....	2193

### Proposed Rules:

39.....	48, 50, 52, 54, 734, 737, 1252, 1254, 1258, 1260, 1262, 1265, 1267, 1269, 1621, 1623, 1627, 3217
71.....	1276, 1279, 4221, 4222, 4798

### 15 CFR

740.....	2875
742.....	2875, 4781
744.....	722, 2883
750.....	2875
774.....	2875

### Proposed Rules:

4.....	56
922.....	2254, 2269

### 16 CFR

1500.....	2193
-----------	------

### Proposed Rules:

1015.....	59
-----------	----

### 18 CFR

375.....	1183
----------	------

388.....1183	27.....780	17.....4795	1006.....4100
<b>Proposed Rules:</b>	28.....780	<b>Proposed Rules:</b>	<b>Proposed Rules:</b>
35.....4464	30.....780	17.....1288	424.....3678
37.....4464	<b>28 CFR</b>	<b>39 CFR</b>	<b>43 CFR</b>
<b>19 CFR</b>	16.....725	20.....1206	3160.....2906
360.....1183	31.....4783	265.....2896	<b>44 CFR</b>
<b>Proposed Rules:</b>	<b>29 CFR</b>	<b>Proposed Rules:</b>	204.....40
133.....4800	1.....2221	111.....2293, 4231	206.....40
<b>20 CFR</b>	3.....2221	501.....1294	207.....40
<b>Proposed Rules:</b>	4.....2221	<b>40 CFR</b>	<b>Proposed Rules:</b>
725.....739	5.....2221	19.....3633	206.....4064
<b>21 CFR</b>	6.....2221	22.....2230	<b>45 CFR</b>
201.....2193	500.....2221	51.....3078, 5181	98.....3185
801.....2193	505.....2221	52.....22, 792, 912, 1206, 1603,	1171.....44
866.....3609	516.....2221	2237, 2239, 3078, 3171,	1230.....1606
870.....4151	519.....2221	3637, 3639	2554.....1606
884.....1598	520.....2221	61.....5142	<b>46 CFR</b>
888.....2217	525.....2221	68.....4594	502.....46
1100.....2193	530.....2221	81.....1603, 2239, 3172	503.....2248
1308.....2218	547.....2221	124.....2230	<b>Proposed Rules:</b>
<b>Proposed Rules:</b>	549.....2221	171.....952	393.....3250
101.....4225	553.....2221	180.....1208, 2897, 2900	<b>47 CFR</b>
117.....4803	570.....2221	300.....2760	0.....4185
1308.....2280	575.....2221	704.....3641	1.....4185
<b>22 CFR</b>	578.....2221	1700.....3173	<b>Proposed Rules:</b>
35.....3168	580.....2221	<b>Proposed Rules:</b>	1.....3258, 4269
103.....3168	801.....2221	Ch. I.....3518	2.....3258
120.....15	825.....2221	7.....2294	15.....3258
121.....2889	1614.....654, 3170	9.....2294	25.....3258
123.....15	1910.....2470	35.....2933	30.....3258
126.....15	1915.....2470	52.....792, 1296, 2295, 2305,	54.....4275
127.....3168	1926.....2470	2308, 3233, 3234	64.....4837
138.....3168	<b>30 CFR</b>	62.....3554	73.....3279
241.....2218	<b>Proposed Rules:</b>	63.....4232	101.....3258
305.....1185	57.....2284	81.....792, 2308, 3234	<b>48 CFR</b>
<b>Proposed Rules:</b>	70.....2284	122.....4233	2.....4709, 4716
62.....4120	72.....2284	123.....4233	3.....4709, 4716, 4717
121.....4226	75.....2284, 2285	141.....4805	4.....4709, 4717
<b>23 CFR</b>	250.....1284	143.....4805	5.....4709, 4724
<b>Proposed Rules:</b>	<b>31 CFR</b>	320.....3388, 3512	6.....4724
655.....770	538.....4793	372.....1651	7.....4709
<b>24 CFR</b>	<b>Proposed Rules:</b>	702.....4825	8.....4709
15.....3619	40.....67	710.....4255	9.....4709
35.....4151	<b>32 CFR</b>	721.....80	12.....4709
891.....3623	154.....1192	<b>42 CFR</b>	14.....4709
<b>26 CFR</b>	286.....1192	10.....1210	15.....4709
1.....2046, 2124	706.....3623	401.....4974	16.....4709
31.....2046	<b>Proposed Rules:</b>	405.....4974	17.....4709
301.....2046, 2124	2004.....3219	409.....4504	18.....4724
<b>Proposed Rules:</b>	<b>33 CFR</b>	410.....4504	19.....4716, 4724
1.....1629, 1645	110.....2893	414.....24	27.....4709
<b>27 CFR</b>	165.....20, 3625, 4794	416.....24	31.....4732
16.....2892	Ch. II.....1860	418.....4504	32.....4709
18.....1108	401.....4172	419.....24	42.....4709
19.....1108	<b>Proposed Rules:</b>	422.....4974	48.....4709
24.....1108	100.....2291, 2930	423.....4974	49.....4709
25.....1108	117.....787	431.....24, 37	52.....4709, 4717, 4724
26.....1108	165.....789, 4229	433.....24, 37	Ch. I.....4708, 4734
27.....1108	401.....1285	438.....24, 37	504.....46
28.....1108	402.....1287	440.....24, 37, 4504	516.....2249
30.....1108	<b>36 CFR</b>	457.....24, 37	552.....2249
<b>Proposed Rules:</b>	13.....3626	478.....4974	<b>49 CFR</b>
18.....780	1195.....2810	482.....24	360.....5292
19.....780	<b>Proposed Rules:</b>	484.....4504	365.....5292
24.....780	1.....1647	485.....4504	366.....5292
25.....780	<b>38 CFR</b>	486.....24	368.....5292
26.....780	3.....4173	488.....24, 4504	383.....2915
		495.....24, 37	384.....2915
		510.....180	
		512.....180	
		1000.....4100	
		1001.....4100	
		1002.....4100	

---

385.....	5292	571.....	3853	648.....	3676	600.....	4278
387.....	5292			<b>Proposed Rules:</b>		622.....	.810, 1308
390.....	5292	<b>50 CFR</b>		17.....	1296, 1657, 1665, 1677	660.....	.812
1002.....	4796	17.....	3186	217.....	.684	679.....	.2916
<b>Proposed Rules:</b>		635.....	3209	223.....	3694, 4276		
1300.....	.805	229.....	3655	224.....	4276		



---

---

**LIST OF PUBLIC LAWS**

---

**Note:** No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List January 11, 2017

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